



Agricultural Marketing Service

7 CFR Part 205

[Doc. No. AMS-NOP-17-0065; NOP-17-02]

RIN 0581-AD09

National Organic Program (NOP); Strengthening Organic Enforcement

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rulemaking amends the United States Department of Agriculture (USDA) organic regulations to strengthen oversight and enforcement of the production, handling, and sale of organic agricultural products. The amendments protect integrity in the organic supply chain and build consumer and industry trust in the USDA organic label by strengthening organic control systems, improving farm to market traceability, and providing robust enforcement of the USDA organic regulations. Topics addressed in this rulemaking include: applicability of the regulations and exemptions from organic certification; National Organic Program Import Certificates; recordkeeping and product traceability; certifying agent personnel qualifications and training; standardized certificates of organic operation; unannounced on-site inspections of certified operations; oversight of certification activities; foreign conformity assessment systems; certification of producer group operations; labeling of nonretail containers; annual update requirements for certified operations; compliance and appeals processes; and calculating organic content of multi-ingredient products.

DATES: *Effective date:* March 20, 2023

Implementation date: March 19, 2024.

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SUPPLEMENTARY INFORMATION:

I. Executive Summary

This rulemaking amends several sections of the USDA organic regulations, 7 CFR Part 205, to strengthen oversight of the production, handling, certification, marketing, and sale of organic agricultural products as established by the Organic Foods Production Act of 1990 (OFPA, or “the Act”).¹ When implemented, this rulemaking will improve organic integrity across the organic supply chain, and benefit stakeholders throughout the organic industry. These amendments close gaps in the current regulations to build consistent certification practices to deter and detect organic fraud, and improve transparency and product traceability. In addition, the amendments will assure consumers that organic products meet a robust, consistent standard and reinforce the value of the organic label.

The need for this rulemaking is driven by organic market growth and increasingly complex organic supply chains. Today’s organic market is characterized by long—and often global—supply chains where organic products are handled by many businesses before reaching the consumer. Often, these businesses are not certified organic—and therefore have no oversight from the USDA or USDA-accredited certifying agents. The absence of direct enforcement over some entities in the organic supply chain, in combination with price premiums for organic products, has created the opportunity for

¹ The Organic Foods Production Act of 1990, 7 U.S.C. 6501–6524, is the statute from which the Agricultural Marketing Service derives authority to administer the NOP and authority to amend the regulations as described in this rulemaking. This document is available at: <https://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter94&edition=prelim>

organic fraud. The amendments in this rulemaking are designed to mitigate the occurrence of organic fraud.

The Agricultural Marketing Service (AMS) is confident in the integrity and value of the USDA organic seal. Consumers can trust the organic label due to a rigorous oversight system that operates globally. However, the challenges of modern organic supply chains demand action to strengthen enforcement and uphold the integrity of the USDA organic label.

This rulemaking strengthens enforcement of the USDA organic regulations through several actions mandated by the Agriculture Improvement Act of 2018:

1. Reduce the types of uncertified entities in the organic supply chain that operate without USDA oversight—including importers, certain brokers, and traders of organic products. This will safeguard organic product integrity and improve traceability.
2. Require the use of NOP Import Certificates for all organic products entering the United States. This change expands the use of NOP Import Certificates to all organic products imported into the United States, improving the oversight and traceability of imported organic products.
3. Clarify the NOP's authority to oversee certification activities, including the authority to act against an agent or office of a certifying agent. Additionally, certifying agents must notify the NOP upon opening a new office, which will allow the NOP to provide more effective and consistent oversight of certifying agents and their activities.

Additionally, this rule includes several essential actions that work in alignment with the provisions above to further strengthen enforcement of the USDA organic regulations:

1. Require that nonretail containers used to ship or store organic products are labeled with organic identity and are traceable to audit trail documentation.

This information will clearly identify organic products, reduce the mishandling of organic products, and support traceability.

2. Require certifying agents to conduct unannounced inspections of at least 5% of the operations they certify, complete mass-balance audits during annual on-site inspections, and verify traceability back to the previous certified operation in the supply chain during annual on-site inspections.
3. Require certifying agents to issue standardized certificates of organic operation generated from the USDA's Organic Integrity Database (OID); this will simplify the verification of valid certificates of organic operation. Certifying agents must also keep accurate and current certified operation data in OID, which will further support verification of operations' certified status.
4. Clarify how certified operations may submit changes to their organic system plan, with the goal of reducing paperwork burden for organic operations and certifying agents. This rule also builds consistency in certification practices by clarifying that certifying agents must conduct on-site inspections at least once per calendar year.
5. Establish specific qualification and training requirements for certifying agent personnel, including inspectors and certification reviewers. Requiring that personnel meet minimum education and experience qualifications and requiring continuing education will ensure high-quality and consistent certification activities across all certifying agents.
6. Clarify conditions for establishing, evaluating, and terminating equivalence determinations with foreign government organic programs, based on an evaluation of their organic foreign conformity systems. This will ensure the compliance of organic products imported from countries that have organic trade arrangements or agreements with the United States.

7. Clarify that the NOP may initiate enforcement action against any violator of the OFPA, including uncertified operations and responsibly connected parties; clarify what actions may be appealed and by whom; and clarify NOP's appeal procedures and options for mediation (alternative dispute resolution).
8. Specify certification requirements for producer group operations, to provide consistent, enforceable standards and ensure compliance with the USDA organic regulations. Producer groups must meet certain criteria to qualify for certification, and must use an internal control system to monitor compliance.
9. Clarify the method of calculating the percentage of organic ingredients in a multi-ingredient product to promote consistent interpretation and application of the regulation.
10. Require certified operations to develop and implement improved recordkeeping and organic fraud prevention processes and procedures; require certifying agents to conduct supply chain traceability audits and to develop and implement information-sharing processes.

Costs and Benefits

AMS estimates the following costs and benefits of this rule:

Costs and Benefits of SOE Rulemaking				
	Average Annual Cost^a		Total Cost^b	
	<i>3% Discount Rate</i>	<i>7% Discount Rate</i>	<i>3% Discount Rate</i>	<i>7% Discount Rate</i>
Domestic Costs	\$10,548,510	\$7,884,601	\$158,227,651	\$118,269,011
Foreign Costs	\$8,769,681	\$6,550,892	\$131,545,210	\$98,263,398
Total Costs	\$19,318,191	\$14,435,494	\$289,772,861	\$216,532,409
Benefits	\$32,944,812	\$24,272,099	\$494,172,179	\$364,081,491

^a Estimated annual averages of the 15-year Net Present Value domestic costs discounted at 3 and 7 percent

^b Estimated total domestic costs for affected industry in Net Present Value discounted at 3 and 7 percent

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II. Background

A. Authority

The Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501–6524), authorizes the Agricultural Marketing Service (AMS) to establish and maintain national standards governing the marketing of organically produced agricultural products. AMS administers these standards through the National Organic Program (NOP). Final regulations implementing the NOP, also referred to as the USDA organic regulations, were published on December 21, 2000 (65 FR 80548) and became effective on October 21, 2002.² Through these regulations, AMS oversees national standards for the production, handling, labeling, and sale of organically produced agricultural products.

B. Purpose and Need for the Rule

Since full implementation of the USDA organic regulations, the organic industry has experienced significant change. Both demand for and sales of organic products have risen steadily; total U.S. sales of organic products reached more than \$63 billion in 2021.³ The number of businesses producing, handling, marketing, and selling organic products has also grown to meet consumer demand. Rapid growth has attracted many businesses to the USDA organic label and increased the complexity of global organic supply chains.

Complexity makes oversight and enforcement of the organic supply chains difficult because organic products are credence goods, which means that their organic attributes, or “integrity,” cannot be easily verified by consumers or businesses who buy organic products for use or resale. The elements needed to guarantee organic integrity—transparent supply chains, trusted interactions between businesses, and mechanisms to verify product legitimacy—are more difficult to achieve in the increasingly complex modern organic industry. This is further compounded by inconsistent interpretation and

² 7 CFR Part 205 National Organic Program; Final Rule. December 21, 2000. Available on the AMS website: <https://www.federalregister.gov/documents/2000/12/21/00-32257/national-organic-program>

³ Organic Trade Association, Organic Industry Survey, 2022.

implementation of the USDA organic regulations, caused by a lack of clarity in some portions of the regulation.

AMS is confident in the integrity and value of the USDA organic seal. Consumers can trust the organic label due to a rigorous oversight system that operates globally. However, the above challenges sometimes cause mishandling of organic products, where integrity is compromised due to improper handling. Additionally, high demand for organic products, the absence of direct enforcement over some entities in the organic supply chain, and organic price premiums increase the opportunity and incentive for organic fraud (when nonorganic products are deceptively represented as organic).

This rule addresses these risks and challenges by expanding oversight to higher-risk portions of organic supply chains, requiring organic operations to implement traceability and verification best practices, and clarifying oversight and enforcement practices to ensure more consistent implementation by certifying agents. This rule will help prevent loss of organic integrity—which can occur both through unintentional mishandling of organic products, and intentional fraud meant to deceive—and strengthen the trust consumers, farmers, and businesses have in the USDA organic label.

Mishandling of Organic Products and Complex Supply Chains

One of the most common risks to the integrity of an organic product is mishandling—when an entity unintentionally compromises the unique attributes that make a product organic. Once organic integrity is compromised, that product can no longer be sold as organic, and both its unique attributes and price premium are forfeit. Mishandling can occur at any point in a supply chain, including production, handling, transport, storage, sale, and processing. Examples of mishandling that can cause a loss of integrity include exposure to pesticides, fertilizers, fumigants, or cleaning agents that are not permitted in organic production; mixing (“commingling”) of organic and nonorganic products; relabeling or repackaging with incorrect identification; and inability to

demonstrate organic status due to poor or incomplete information in records or transaction paperwork. The likelihood of such mishandling is greater in long, complex supply chains where many businesses, including businesses not certified organic, handle and sell organic products.

When the organic regulations were published in 2000, organic products were marketed mostly locally or regionally, and supply chains tended to be short and transparent; for example, farm to wholesale to retail to consumer. Demand and sales have grown considerably since then. This significant market growth has attracted more producers, handlers, product suppliers, importers, brokers, distributors, and others to the organic market. Consider the example of an organic egg supply chain in the United States, beginning with the production of certified organic corn and ending with the sale of eggs to the consumer. This demonstrates the typical entities and transactions in an organic supply chain under the existing regulations:

- A certified organic farm produces organic corn.
- The corn is transported via an uncertified truck to a local grain elevator, where it is aggregated with other organic corn from nearby producers.
- An uncertified commodity trader buys the corn.
- The corn is transported via uncertified truck to an uncertified storage facility; both transport and storage are subcontracted and are not owned by the commodity trader.
- The commodity trader sells the corn to a certified organic grain supplier; the two parties remain anonymous because they use an uncertified broker to facilitate the transaction.
- The corn is transported via uncertified rail and river barge to the grain supplier; it is transloaded and stored temporarily several times before being delivered to the certified grain supplier.

- The certified organic grain supplier stores the corn and combines it with imported organic corn purchased from an importer via an uncertified broker.
- The certified grain supplier sells the corn to a certified organic feed processor; the corn is transported via an uncertified truck.
- The certified processor combines the corn with several other ingredients to create organic chicken feed.
- The certified processor sells the feed to a certified organic egg producer and transports it via an uncertified truck.
- The certified organic egg producer sells organic eggs to an uncertified distributor.
- The uncertified distributor sells the organic eggs to a retailer prior to final sale to the consumer.

This example illustrates the supply chain for a single ingredient—organic feed corn. The supply chain for the organic eggs at the end of this example is even more complex because it includes other ingredients that go into the chicken feed (e.g., soybean meal, oats, wheat, seed oils). Many of these ingredients are sourced both domestically and internationally. Each ingredient has its own unique supply chain; together they create a complex web converging on a single organic product. It is largely because of this complexity that this rule introduces more specific traceability, verification, oversight, and enforcement practices for high-risk portions of organic supply chains.

Organic Fraud

In addition to mishandling, a growing risk to organic integrity is fraud—the deceptive representation, sale, or labeling of nonorganic agricultural products as organic. High demand for organic products, the absence of direct enforcement over some entities in the organic supply chain, and organic price premiums have increased the opportunity and incentive for organic fraud. Both NOP and organic stakeholders have uncovered organic fraud in organic supply chains, particularly in organic grain and oilseed supply

chains. Because such supply chains are complex and involve multiple changes in ownership of high demand products, the incentive for fraud is high. Federal investigations show that organic grain and oilseed fraud can lead to tens of millions of dollars in fraudulent sales within just a few months. The following examples highlight some of the types of organic fraud that this rule seeks to prevent. The examples also demonstrate the magnitude of total organic fraud and how this rule's additional oversight and enforcement mechanisms will reduce fraud.

- In 2019, four individuals were sentenced to prison terms for their roles in an organic grain fraud ring. The charges were brought by the U.S. Attorney's Office for the Northern District of Iowa. All four were sentenced to prison terms. The lead defendant, who was sentenced to more than ten years, pled guilty to defrauding customers in a scheme involving at least \$142 million in nonorganic grains sold as organic. The lead defendant sold fraudulent grain to customers over a period of seven years, claiming the product was organically grown in Nebraska and Missouri.⁴ This rule includes more robust traceability and verification practices that would have helped identify and stop this type of fraud earlier, preventing further sale of the fraudulent products and reducing the impact of the fraud.
- In February 2020, a federal grand jury indicted an individual in South Dakota for allegedly selling \$71 million of nonorganic grains and oilseeds falsely labeled organic between 2012 and 2018.⁵ The defendant pled guilty and was sentenced in 2021 to 51 months in federal prison. He was also ordered to pay more than \$15

⁴ <https://www.justice.gov/usao-ndia/pr/field-schemes-fraud-results-over-decade-federal-prison-leader-largest-organic-fraud>

⁵ <https://www.wisfarmer.com/story/news/2020/02/18/south-dakota-man-indicted-71-million-organics-fraud/4801207002/>

<https://www.justice.gov/usao-sd/pr/florida-man-sentenced-conspiracy-commit-wire-fraud-and-money-laundering>

million in restitution. The fraud ring spanned multiple states. After NOP revoked the business' organic certifications, the responsible parties established new brokerage firms to continue their fraud. Under the current organic regulations, these brokerages did not require organic certification and NOP had no oversight of their activities. This rule will require the certification and oversight of brokers like those involved in this case. This would allow the NOP to identify and prevent the fraud, minimizing damage to the U.S. market.

- In 2017, an investigation revealed three shipments of imported “organic” corn and soybeans—each weighing between 36 and 46 million pounds—were fraudulently labeled as organic. The associated transaction records indicated that all three shipments originated from producers in the Black Sea region that were not certified organic, and that the shipments were originally sold at lower conventional prices. In one case, a shipment of soybeans had been fumigated with aluminum phosphide, which is prohibited for use in organic production and handling. By the time this fraud was discovered, about 21 million pounds of this same shipment of soybeans had already been distributed—primary to organic producers as livestock feed.⁶ This rule will require the use of NOP Import Certificates to verify the source and integrity of organic imports, which will help detect and prevent fraudulently labeled imports, such as those in this example, from entering domestic supply chains.
- In July 2022, a Minnesota farmer was indicted for growing and selling fraudulent organic grains worth more than \$46 million. The farmer was certified organic but was growing grains with synthetic fertilizers and pesticides in violation of the USDA organic regulations. He sold this conventional grain (both what he

⁶ https://www.washingtonpost.com/business/economy/the-labels-said-organic-but-these-massive-imports-of-corn-and-soybeans-werent/2017/05/12/6d165984-2b76-11e7-a616-d7c8a68c1a66_story.html

produced conventionally as well as conventional grain he purchased) as organic, fraudulently presenting his certificate of organic operation to claim the grain was organic and withholding the grain's true status from buyers.⁷ This rule includes more robust traceability and verification practices that would have helped identify and stop this type of fraud earlier, preventing further sale of the fraudulent products and reducing the impact of the fraud.

In several of the above examples, fraudulent livestock feed was sold to certified organic livestock producers, magnifying the effects of the fraud. NOP continues to investigate complaints and multiple cases of organic fraud at the production and handling levels. These examples demonstrate the magnitude of fraud that NOP intercepts with current oversight and enforcement techniques. SOE will significantly bolster the oversight and enforcement mechanisms that NOP, certifying agents, and operations have at their disposal. In the fraud cases discussed above, these mechanisms would have allowed earlier fraud detection and more effective enforcement action and would have greatly reduced or even prevented the fraud.

Patterns in USDA Organic Certification and Organic Imports

The scope and distribution of potential organic fraud can also be seen in changes in the number of operations certified to the USDA organic standards and changes in the amount of organic imports from certain regions. Two recent NOP efforts show both the potential type and magnitude of fraud in the marketplace; more importantly, they also demonstrate the potential of improved oversight and enforcement mechanisms.

In 2018 and 2019, NOP began making changes to improve oversight of organic imports, especially grain and oilseed imports from the Black Sea region. NOP conducted

⁷ <https://www.justice.gov/usao-mn/pr/cottonwood-county-farmer-charged-46-million-organic-grain-fraud-scheme>

farm-level yield analysis to compare expected and actual yield, supply chain research to better understand the roles and relationships of high-risk entities, and targeted import surveillance to investigate credible reports of suspected fraud. As a result of this heightened oversight and enforcement action, at least 180 operations (60 percent) in the Black Sea region have lost their organic certification. In 2016, imports from the Black Sea region represented 49 percent of the total dollar value of imported organic grain and oilseeds (including corn, soybeans, wheat, barley, sunflowers, flaxseed, and peas). In 2018, imports of these grains and oilseeds from the region had dropped to 21 percent of the total dollar value. The steep drop in organic certification and downward supply trend in the Black Sea region give an indication of the magnitude and type of fraud, as well as the success of stronger oversight and enforcement strategy. Despite this enforcement success, key gaps in oversight remain, such as uncertified entities in import supply chains and non-mandatory use of NOP Import Certificates. This rule will help close these gaps and bolster NOP's ability to detect and prevent fraudulent organic imports.

In January 2021, AMS announced it would end its U.S.–India organic recognition, which had allowed India's Agricultural and Processed Food Products Export Development Authority (APEDA) to accredit certifying agents to provide USDA organic certification in India. AMS ended this recognition because NOP audits consistently found India's organic control system to be insufficient to protect the integrity of the USDA organic seal. In late 2020, prior to the end of U.S.-India recognition, there were 4,023 operations certified to the USDA organic standard in India. Operations formerly certified by AEDPA-accredited certifying agents were given an 18-month transition period to become certified by a USDA-accredited certifying agent. Since the end of the transition period in July 2022, only 1,471 operations in India remain certified to the USDA organic standard. Because failure to become recertified may indicate an inability to comply with the USDA organic regulations, this significant (63 percent) drop in the

number of certified operations may indicate the general volume of noncompliant activity (including mishandling and fraud) that may have been taking place under the former recognition. Additionally, following the end of the U.S. –India recognition, imports of certified organic products from India has dropped from an average per quarter value of \$15.6 million to \$9.4 million, a 39 percent decrease. This drop in import value suggests that a significant number of organic imports from India may not have been fully compliant with the USDA organic standard. The end of the U.S.-India recognition demonstrates both the magnitude of potential fraud in the market, and how more effective oversight (in this case, certification only by USDA-accredited certifying agents) can successfully safeguard the integrity of the USDA organic label. Despite this success, there are still gaps in the oversight of foreign-accredited certifying agents and imports from these countries. This rule will allow NOP to more fully implement its oversight authority by codifying specific procedures for evaluating, accepting, and continuing equivalency or recognition with foreign organic programs.

These examples demonstrate how applying oversight and enforcement best practices can reduce organic fraud. SOE will reduce fraud by codifying best practices in critical areas—exemptions from certification, import oversight, traceability, recordkeeping, inspections and audits, oversight of certifying agents, and assessment of organic trade partners. Additionally, the examples above only show the positive results of improved oversight and enforcement at the federal level; SOE will build upon this success by requiring certifying agents and organic operations to use similar techniques. This means proven oversight and enforcement techniques will be deployed closer to where fraud occurs, which will facilitate earlier detection, stop more fraud before it cascades further into supply chains, and more directly deter fraudulent actors. Because this rule codifies best practices and requires key parties in organic supply chains use these practices, AMS expects that SOE’s benefits will exceed those demonstrated in the examples above.

C. History

In response to their experiences in the organic system, stakeholders have called for the NOP to take steps to improve oversight of organic systems and enforcement of the USDA organic regulations. Commonly cited areas for improvement include certification of excluded handlers, organic import oversight, fraud prevention, organic trade arrangements, and organic inspector qualifications. Public discussions on many topics included in this rule occurred during multiple National Organic Standards Board (NOSB) meetings.⁸

This rule seeks to strengthen enforcement of the USDA organic regulations and protect the integrity of the organic label by (1) strengthening organic control systems; (2) improving organic import oversight; (3) clarifying organic certification standards; and (4) enhancing supply chain traceability. AMS identified the need for these changes through:

- Direct experience in administering the NOP, particularly complaint investigations and audits of accredited certifying agents;
- The Agriculture Improvement Act of 2018,⁹ which amended the OFPA.
- Recommendations of a 2017 Office of Inspector General report;¹⁰
- Recommendations of the NOP's federal advisory committee, the National Organic Standards Board (NOSB); and
- Industry stakeholder and consumer feedback.

AMS expects the amendments will bring more effective oversight and enforcement, improve organic integrity and product traceability, clarify existing standards to ensure

⁸ The April 2021 NOSB meeting is the most recent example of a public discussion to address fraud concerns in the organic supply chain. A discussion document, meeting transcripts, and public comments are available at <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-crystal-city-va-0>

⁹ The Agriculture Improvement Act of 2018, Public Law No: 115-334, is available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

¹⁰ USDA Office of Inspector General Audit Report 01601-0001-21: National Organic Program International Trade Arrangements and Agreements. September 2017: <https://www.usda.gov/sites/default/files/01601-0001-21.pdf>

fair competition, bolster consumer trust in the organic label, reduce organic fraud, and support continued industry growth. Information about each amendment is described in more detail below.

D. Public Comment

AMS published the Strengthening Organic Enforcement proposed rule on August 5, 2020, opening a 60-day public comment period. AMS received more than 1,500 public comments from a variety of stakeholders, including certifying agents, certified organic producers and handlers, uncertified handlers, retailers, organic inspectors, trade associations, organic advocates, scientific organizations, government organizations, and consumers. The majority of public comments supported the proposed amendments and agreed that the rule is needed to improve oversight and enforcement, drive consistent implementation of the organic regulations, and reduce organic fraud.

Many stakeholders provided meaningful feedback about the proposed policy revisions, including recommendations to improve the rule through greater specificity and clarity. Others discussed how the proposed amendments would affect them or suggested alternatives to the proposed policies. Popular topics of discussion included the need for certification; excluded handlers; exemptions from certification; implementation of the mandatory NOP Import Certificate requirements; supply chain traceability audits; recordkeeping and verification requirements; fraud prevention plans for certified operations; oversight of producer groups; qualifications and training requirements for certifying agent personnel; labeling of nonretail containers; and unannounced inspections.

Some comments also discussed the proposed implementation timeframe of one year after publication of the final rule. Some comments asked AMS to implement the rule immediately, while others agreed that a one-year timeframe is reasonable and gives stakeholders time to comply with the new requirements. A few comments noted that some parts of the rule may require more than one year to implement and asked AMS to

consider this in the final rule. Few comments addressed the costs and benefits of the rule in detail, but many comments noted in general that the costs of the rule are acceptable and outweighed by the benefits.

AMS took these public comments into consideration when revising the policy, implementation timeframe, and cost-benefit analysis of this rulemaking. For more information on the comments received and AMS's response to specific comments, refer to "III. Overview of Amendments."

E. Terminology

Throughout this rule, AMS refers to four concepts—organic integrity, organic fraud, audit trails, and supply chain traceability—which are integral to the purpose of this rule.

AMS is explaining these concepts upfront to assist reader understanding:

- **Organic integrity:** The unique attributes that make a product organic and define its status as organic. A product that fully complies with the USDA organic regulations has integrity, and its organic qualities have not been compromised.
- **Organic fraud:** Deceptive representation, sale, or labeling of nonorganic agricultural products or ingredients as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" (7 CFR 205.2).
- **Audit trail:** Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as "100 percent organic," the organic ingredients of any agricultural product labeled as "organic" or "made with organic (specified ingredients)" or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement (7 CFR 205.2).
- **Supply chain traceability:** The ability to identify and track the movement, sale, custody, handling, and organic status of an agricultural product along a supply

chain. Supply chain traceability audits are used to verify an agricultural product's compliance with the USDA organic regulations.

F. Does this Action Apply to Me?

You may be affected by this action if you are engaged in the organic industry.

Potentially affected entities may include, but are not limited to, the following:

- Individuals or business entities that are considering organic certification;
- Existing production and handling operations that are currently certified organic under the USDA organic regulations;
- Brokers, traders, and importers of organic products that are not currently certified under the USDA organic regulations;
- Operations that use non-retail containers for shipping or storing organic products;
- Retailers that sell organic products;
- Operations that receive or review certificates of organic operation to verify compliance with USDA organic regulations;
- USDA-accredited certifying agents, inspectors, and certification review personnel;
- Operations that import organic products into the United States; and/or
- Operations that export organic products to the United States and the corresponding certifying agents.

This list is not exhaustive but identifies key entities likely to be affected by this action. Other types of entities may also be affected. To determine whether you or your business may be affected by this action, you should carefully examine the regulatory text and discussion below.

G. Compliance Date

AMS is establishing a compliance date for this final rule of March 19, 2024, or 12 months after the effective date of this final rule. This means that all entities affected by

this rule, including certified operations and certifying agents, must comply with the provisions of this final rule by this date. This also means that operations requiring organic certification because of this final rule must be certified by the compliance date. AMS is setting this compliance date to allow affected entities time to read and understand this final rule, obtain organic certification if needed, and prepare for and implement other changes in this final rule.

III. Overview of Amendments

A. Applicability and Exemptions from Certification.

The table below includes the regulatory provisions related to this section of the rule.

A discussion of the policy follows.

Section	Final Regulatory Text
205.2	Terms Defined. Definitions for <i>Handle, Handler, Handling operation, and Retail establishment</i> .
205.100	What has to be certified. Paragraph (a).
205.101	Exemptions from certification. Entire section.
205.310	Agricultural products produced or processed by an exempt operation. Paragraphs (a) and (b).

The USDA organic regulations require organic certification of businesses that sell, process, or package organic agricultural products as handling operations. This rulemaking clarifies that most operations that operate in the middle of organic supply chains must be certified organic. This may include entities that sell, trade, distribute, or import organic products. The activities of these operations may affect organic integrity; therefore, certification is necessary to assure consumers that organically produced products meet a consistent standard. In addition to clarifying who needs certification, this rulemaking also provides limited exemptions to organic certification for certain entities and activities that present a low risk to organic integrity.

This action may affect noncertified operations that handle organic products, sell organic products, or facilitate the sale or trade of organic products on behalf of a seller or oneself; certified organic operations; organic inspectors; and certifying agents. Readers should carefully examine the regulatory text and policy discussion to determine if they are affected.

Background

The organic market has grown considerably since the USDA organic regulations took effect in 2002. The Organic Trade Association reports that total U.S. organic sales grew from \$3.4 billion in 1997 to \$61.9 billion in 2020.¹¹ This growth has created increasingly complex organic supply chains as additional domestic and international businesses choose to produce and sell organic products for the U.S. market. Some segments of organic supply chains remain uncertified under current regulation, creating gaps in oversight, increasing the opportunity for fraud, and complicating enforcement by the USDA and its enforcement partners.

Oversight and enforcement of organic supply chains are challenging because organic products are credence goods, which means that their organic attributes, or “integrity,” cannot be easily verified by an individual. Guaranteeing organic integrity requires transparent supply chains, trusted interactions between businesses, and mechanisms to verify product legitimacy. This is best accomplished via certification, which requires operations to follow traceability and verification practices, and provides regular oversight in the form of audits and annual inspection. This rulemaking broadens the scope of who must be certified, opening more of the organic supply chain to oversight and mitigating the risks of noncertified businesses handling organic product.

¹¹ Organic Trade Association, Organic Industry Survey, 2018–2021

OFPA authorizes the USDA to regulate and enforce the production, handling, and sale of organic products (7 U.S.C. 6503). This includes activity within organic supply chains, from production through final sale to the consumer.¹² AMS is exercising its authority to regulate entities in organic supply chains by requiring certification of some types of currently noncertified operations. This action is mandated by the 2018 Farm Bill, which states that the USDA must “issue regulations to limit the type of organic operations that are excluded from certification under section 205.101” of the organic regulations.¹³ This rulemaking supports the OFPA’s purpose “to assure consumers that organically produced products meet a consistent standard (7 U.S.C. 6506(a)(11)).”

Who needs to be certified?

Section 205.100(a) of the organic regulations states that any operation that produces or handles organic agricultural products must be certified organic. This means that operations conducting activities described in the definition of *handle* must be certified organic and must follow all applicable portions of the OFPA and the USDA organic regulations. In general, *handle* means to “sell, process, or package” organic agricultural products. Limited exemptions for operations that handle organic agricultural products are described in § 205.101(a)–(h).

The definition of *handle* includes the term *processing*, which is defined in § 205.2.¹⁴ Operations that process organic agricultural products must be certified. *Handle* further explains what to “sell” and “package” mean by including additional examples of handling activities. The examples represent typical supply chain activities that may affect organic

¹² OFPA and the USDA organic regulations do not provide authority to regulate the transport of organic agricultural products.

¹³ See section 10104(a) of the Agriculture Improvement Act of 2018, Public Law No: 115-334, available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

¹⁴ 7 CFR 205.2 *Processing*. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

integrity. This includes activities where there is physical contact with agricultural products, such as combining, aggregating, culling, conditioning, treating, packing, containerizing, repackaging, labeling, storing, receiving, or loading.¹⁵ Examples of operations that often conduct these activities may include grain elevators; bulk grain handlers; warehouses that cull, label, or repackage; central bakeries or kitchens that serve grocery chains; or ports of entry.

Handle also includes activities where there may not be physical contact with agricultural products, such as selling, trading, facilitating sale or trade on behalf of a seller or oneself, importing to the United States, or exporting from a foreign country for sale in the United States. These activities are included in the definition of *handle* because they have the potential to affect organic integrity. Operations that conduct these activities must be certified (unless exempt per § 205.101). Examples of operations that often conduct these activities may include sales brokers, commodity traders, ingredient sourcers, importers, or exporters.

The definition of *handle* is not an exhaustive list of activities that must be certified. There may be additional activities not listed in the definition that are similar to the listed activities and require certification, or different words or synonyms for the same or similar activities. The absence of a specific term in the definition of *handle* does not mean the activity is not handling or that an operation conducting this activity does not need certification.

What are the certification requirements for handlers?

All certified organic operations must follow the portions of the USDA organic regulations that apply to activities they conduct. Conversely, some portions of the

¹⁵ The regulations at § 205.2 define “label” and “labeling” to explain the type and location of information covered. Labeling as a handling activity refers to the act of applying a label to a product with an organic claim; applying other types of labels, such as for inventory or information accompanying a product, may not need certification.

regulation will not apply to every operation (e.g., a certified operation that only produces crops does not have to follow the livestock requirements of subpart C). Similarly, the scope of a handling operation's certification only covers the activities it conducts. For example, the OSP of a certified importer would likely describe the operation's system to maintain transaction records and audit trails, verify suppliers and NOP Import Certificates, and verify traceability. On-site inspection of such an operation would likely focus on a records review and evaluation, rather than evaluation of physical facilities.

Contractors are sometimes used in the organic industry to provide services to certified operations. Contractors that qualify for an exemption per § 205.101(a)–(f) do not need to be certified. Any contractor performing handling activities on behalf of an operation must be certified or described in the OSP of a certified operation.

It is common for some operations to handle both organic and nonorganic agricultural products (i.e., a *split operation*). For a split operation, only the portion(s) of the operation that produces or handles organic agricultural products must be certified. If a portion of an operation qualifies for an exemption from certification described in § 205.101(a)–(h), only that portion may be exempt, and the remainder of the operation must be certified if it produces or handles organic agricultural products. For example, a grocery store chain's retail locations may be exempt under § 205.101(b) or (c), but its importing and some distribution activities would likely need to be certified.

Organic agricultural products received from an exempt operation

Agricultural products produced or processed on an exempt operation must follow all requirements of § 205.310. This means that an operation receiving products produced or processed by an exempt operation cannot represent the products as certified organic, cannot display the USDA organic seal on the products, and cannot use the products as organic ingredients in a product produced by the receiving operation. In effect, product

received and then processed by an exempt operation loses its certified organic status and cannot be represented as organic.

However, exempt operations may perform limited handling of certified organic products, as described in each exemption at § 205.101; i.e., if an exempt operation handles certified organic products in a manner consistent with its applicable exemption, the products maintain their organic status. This means, for example, that an exempt warehouse may receive, store, and prepare for shipment packaged certified organic products. Conversely, if this warehouse opens or relabels such packaged products, then the certified organic status of the products is lost, and an operation receiving these products must not represent them as certified organic.

The USDA organic regulations require certified operations to implement recordkeeping and verification practices that ensure the integrity of organic agricultural products they receive, including products received from exempt or uncertified operations. Records must trace organic products back through any exempt operations to the last certified operation in the supply chain, and operations must verify their suppliers, including exempt operations. See §§ 205.103(b)(2) and 205.201(a)(3) in the section on Supply Chain Traceability and Fraud Prevention later in this rule.

Exemptions from certification

The USDA organic regulations require certification of any operation that produces or handles organic agricultural products (§ 205.100(a)). However, the regulations provide limited exemptions to certain types of operations that conduct low-risk activities, and are therefore less likely to compromise organic integrity of the agricultural products they handle. These exemptions, and the conditions that must be met to qualify for each, are described in § 205.101.

The USDA organic regulations formerly used the terms “exemption” and “exclusion” to describe activities that do not require organic certification. This final rule

removes use of the term “exclusion” from § 205.101 and throughout the organic regulation to reduce confusion and misinterpretation about who needs to be certified. The term “exemption” is now used exclusively to describe activities that do not require organic certification. Previous “exclusions” listed under former § 205.101(b) have been modified and are now listed under current § 205.101.

Responsibilities of exempt operations

Operations described in § 205.101 are exempt from the requirement to be certified organic under subpart E. However, these exempt operations must still follow all other applicable portions of the organic regulations, including the production and handling requirements of subpart C. For example, a very small vegetable farm may be exempt from certification per § 205.101(a); this means the farm does not have to be certified and inspected annually, and does not have to develop and submit an organic system plan. However, the farm *must* follow the other organic production and handling requirements of subpart C, including soil and fertility practices, crop rotation, weed management, and seed use practices. Exempt operations must also comply with § 205.272 and practices to prevent commingling and contact with prohibited substances.

Exempt operations must also follow the applicable labeling requirements of subpart D. Critically, this means exempt operations *must not* represent the agricultural products they produce or process as certified organic and must not use the USDA organic seal. Additionally, agricultural products produced or processed by an exempt operation must not be identified or represented as organic in a product processed by another operation (See § 205.310, Agricultural products produced or processed on an exempt operation). Additionally, exempt operations are only permitted to perform the limited handling activities described in the applicable exemption; any handling outside of that described in the exemption may result in loss of organic status of products.

Operations that qualify for an exemption may voluntarily choose to become certified. By becoming certified, the operation may market the products it produces and processes as certified organic, display the USDA organic seal on its products, and represent these products as ingredients for use in other organic products.

Like certified operations, exempt operations are subject to penalties for violating the OFPA and the organic regulations. Section 205.100(c) of the organic regulations states that any person or responsibly connected person—including exempt operations—that knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty as specified in 7 CFR 3.91(b)(1)(xxxvi).¹⁶

Recordkeeping by exempt operations

Like certified operations, exempt operations play a critical role in maintaining the integrity of organic products as they travel from production to consumer. Therefore, exempt operations must maintain records of the organic products they produce and handle, including records that: demonstrate that agricultural products identified as organic were organically produced and handled; and verify quantities of organic agricultural products received and shipped or sold. Such records are necessary to maintain an audit trail for organic products; this will facilitate many other provisions of this rule, including supply chain traceability audits (§ 205.501(a)(21)), recordkeeping by certified operations (§ 205.103), on-site inspections (§ 205.403(d)), and fraud prevention plans (§ 205.201(a)(3)). Retail establishments that do not process agricultural products (see definition for *Handle* at § 205.2 and exemption from certification at § 205.101(b)) do not need to maintain such records. Exempt handlers must have required records available

¹⁶ 7 CFR 3.91(b)(xxxvi): Civil penalty for knowingly labeling or selling a product as organic except in accordance with the Organic Foods Production Act of 1990, codified at 7 U.S.C. 6519(c). As of the publication of this rule the civil penalty amount is a maximum of \$20,130 per violation.

and must show those records to a representative of the Secretary upon request. Failure to produce compliant records may lead to enforcement action.

Small producers and handlers

Small organic producers and handlers are exempt from certification at § 205.101(a). This exemption is limited to producers and handlers with gross agricultural income from organic sales of no more than \$5,000 annually. These operations are exempt from certification under subpart E and from submitting an organic system plan, but must follow all applicable organic production and handling requirements of subpart C and labeling requirements of subpart D. This includes the requirements to prevent commingling and prevention of contact with prohibited substances (§ 205.272).

Such operations must not represent the agricultural products they produce or process as certified organic and must not use the USDA organic seal. Agricultural products produced or processed by these exempt operations must not be identified or represented as organic in a product processed by another operation (see § 205.310).

Retail establishments

Retail businesses that handle organic agricultural products and sell directly to consumers may be exempt from certification. To qualify for an exemption, the operation must be a retail establishment and meet the conditions for the exemptions in § 205.101(b) and (c).

The regulations define *retail establishment* to include a range of transaction modes for selling to consumers that commonly occur in the modern marketplace. *Retail establishment* includes restaurants, delicatessens, bakeries, grocery stores, or any retail business with a restaurant, delicatessen, bakery, salad bar, bulk food self-service station, or other eat-in, carry-out, mail-order, or delivery service of raw or processed agricultural products. Retail is commonly described as selling directly to consumers, end-users, or the public. The definition for *retail establishment* aligns with that concept. Businesses

which sell to other businesses (wholesale) do not qualify as retail establishments. Retail establishments may use virtual transactions for sales, but they must also have a physical location for consumers to purchase products.

Only operations that are retail establishments are eligible for the retailer exemptions. The definitions for *handler* and *handling operation* do not include final retailers of agricultural products that do not process agricultural products. This exemption from certification is also reinforced at section 205.101(b), which exempts retail establishments that sell, but do not process, organic agricultural products to consumers.

Section 205.101(c) exempts retail establishments that process certified organic agricultural products at the point of sale to the consumer. Distributors or brand name owners that do not qualify as retail establishments should review the exemptions from certification at § 205.101(e) and (f), as those may apply to their activities.

Retail operations that don't process

Retail establishments that do not process agricultural products are not handlers or handling operations and may be exempt from certification under § 205.101(b). The OFPA and § 205.2 define *processing* as cooking, baking, heating, drying, mixing, grinding churning, separating, extracting, cutting, fermenting, eviscerating, pre-serving, dehydrating, freezing, or otherwise manufacturing, and includes the packaging, canning, jarring, or otherwise enclosing food in a container. A retail establishment that is not processing may do other handling activities without certification. This could include, for example, removing produce from shipping boxes and washing and transferring product to display cases or opening bags of oats and transferring contents to bulk food dispensers. Although a retailer performing such handling activities may be exempt from certification, all retail establishments must comply with § 205.272, which requires measures to prevent commingling of organic products and contact with prohibited substances.

Retail establishments that do not process “100% organic” and “organic” unpackaged products may use the USDA organic seal and/or seal of the certifying agent in retail labeling and display of these unpackaged products (§ 205.308). Retail establishments that do not process “made with organic...” unpackaged products may use that claim in retail labeling and displays (§ 205.309).

Retail establishments that process

Retail establishments that process organic agricultural products may be exempt from certification under § 205.101(c). To qualify for this exemption, a retail establishment must process organic products at the point of final sale to the consumer. This means that the products must be processed and sold in the same physical location. This could include repackaging bulk containers of organic product into individual units for retail sale within an individual grocery store or a retail establishment that prepares ready-to-eat meals and sells them online to consumers from the processing location.

Per § 205.310, organic agricultural products that are processed by exempt retail establishments (such as in the examples above) must not be sold, labeled or represented as “certified” organic, must not display the USDA seal or identify the certifying agent, and must not be used by another operation as ingredients in a certified organic product. Only retail establishments that are certified organic may use the USDA organic seal (or make certified organic claims) on products they process.

This exemption does not cover retail establishments that sell organic products to consumers which are processed at a location separate from the point of sale. This could include, for example, an online retailer that sells products processed at an uncertified facility or a central processing facility that prepares food sold in bakery and deli sections of grocery stores. In these scenarios, the processing facility is not co-located in the same physical location as the point of sale and the retail establishment exemption does not

cover separate processing facilities. The processors would need to be separately certified in order for a retail establishment to sell their products as organic.

In addition, this exemption does not cover retailers that process and sell to consumers only via virtual transactions. “Virtual transaction” describes any form of transaction that does not occur in-person (e.g., telephone, mail-order, and/or online sales). Retailers that process and sell to consumers virtually without having a physical location for retail sales must be certified. These businesses do not meet the definition for retail establishment, and, by extension, the conditions for exemption from certification.

All exempt retail establishments must comply with the requirements of § 205.272, which describes handling requirements to prevent commingling and contact with prohibited substances. In addition, exempt retail establishments that process organic products must follow the labeling provisions specified in § 205.310 and maintain records to (1) demonstrate that agricultural products identified as organic were organically produced and handled; and (2) verify quantities received, sold, or produced from such agricultural products. Exempt handlers must have these records available and must show them to a representative of the Secretary upon request (7 U.S.C. 6519(a)(1)). Failure to produce compliant records may lead to enforcement action.

Operations that handle only products with less than 70 percent organic ingredients

Section 205.101(d) exempts from certification operations that only handle agricultural products with less than 70 percent organically produced ingredients, and operations that only identify organic ingredients on the product informational panel. This exemption is not new policy. It combines two existing exemptions: operations that handle products with less than 70 percent organic ingredients (former § 205.101(a)(3)) and operations that handle products that only identify organic ingredients on the information panel (former § 205.101(a)(4)). AMS combined these exemptions because they cover operations that handle products in the same labeling category (per § 205.305),

and because these operations must follow identical use and labeling requirements.

Operations that qualify for this exemption are exempt from certification under subpart E and from submitting an organic system plan, but must follow all applicable organic production and handling requirements of subpart C and labeling requirements of subpart D. This includes the labeling requirements for products with less than 70 percent organic content (§ 205.305) and the requirements to prevent commingling and prevention of contact with prohibited substances (§ 205.272).

Handlers covered under this exemption must have the records required by § 205.101(i) available and show them to a representative of the Secretary upon request (7 U.S.C. 6519(a)(1)). Failure to produce compliant records may lead to enforcement action. Such operations must not represent the agricultural products they produce or process as certified organic and must not use the USDA organic seal. Agricultural products produced or processed by these exempt operations must not be identified or represented as organic in a product processed by another operation (see § 205.310).

Storing or selling packaged organic products

The movement of packaged and sealed organic products through the supply chain is a lower-risk activity. Packaged products are less likely to be commingled, exposed to contaminants, or tampered with, and alterations are easier to detect. Handling operations that sell, distribute, or store packaged organic agricultural products may be exempt from organic certification. Two exemptions, at § 205.101(e) and (f), apply to limited handling activities involving only organic agricultural products that are in sealed, tamper-evident packaging or containers. The key distinctions between these exemptions are that 205.101(f) covers operations that buy and sell, in addition to receiving, storing and/or preparing for shipment, and that 205.101(f) covers only retail-packaged products versus packaged products that are not in final retail packaging. Tamper-evident packaging or container means that the contents are sealed in a manner where an attempt to break the

seal, access the contents, or reclose the package would be obvious. These exemptions cover only the specified handling activities. These exemptions do not, for example, cover buying, selling, receiving, storing, or loading of unpackaged products; those activities require certification.

The exemption at § 205.101(e) is intended primarily for storage and warehouse facilities. Section 205.101(e) applies to handlers that are only receiving, storing and/or preparing for shipment products that are received in and remain in sealed, tamper-evident packaging until the products leave their custody. This allowance may cover, for example, warehouses and storage facilities, including some cold storage facilities that only receive and store packaged products and prepare them for shipment to another entity. Examples of tamper-evident packaging include produce boxes with “DO NOT TAMPER WITH” tape placed across the box flaps, sealed bulk bags of flour, or sealed drums and totes of olive oil. Storage facilities or warehouses that receive products that are not in sealed, tamper-evident packaging must be certified.

The exemption at § 205.101(f) is intended primarily for distributors. Section 205.101(f) applies to handlers that only buy, sell, receive, store and/or prepare for shipment retail-packaged organic agricultural products. This allowance may cover, for example, some distributors, brand name owners, and sales brokers that purchase and/or receive products in their finished retail packaging. Products must be received in and remain in the final retail packaging without alteration throughout their custody. This exemption does not apply to sales brokers, traders, or other handlers that buy and sell products that are not in their final retail packaging.

Preparing for shipment is an activity that is covered under both exemptions at § 205.101(e) and (f). This may include various tasks that must be performed with the sealed, tamper-evident packaging remaining intact and without altering product contents or any retail labeling. Examples of preparing for shipment include putting packaged

products into shipping containers, applying internal tracking numbers, shrink-wrapping shipping cartons to a pallet, breaking down pallets of fully packaged products, adding protective packaging to nonretail containers or retail displays of organic products, packing individual packaged products onto a shipping pallet, loading/unloading packaged products onto or from transport vehicles, and placing individual retail packages into a retail display which the certifying agent of the last certified handling operation has verified as compliant.

Handlers that qualify for an exemption at § 205.101(e) or (f) must use practices for preventing commingling and contamination of organic products, in compliance with § 205.272. In addition, exempt handlers must have records available and must show those records to a representative of the Secretary upon request, to show that organic products are organically produced and handled and to verify quantities of organic product received and shipped or sold. Failure to produce compliant records may lead to enforcement action.

Customs brokers

Section 205.101(g) exempts Customs brokers from organic certification. Customs brokers facilitate the entry of products into the United States by helping meet import documentation and filing requirements and by acting as intermediaries between importers and the U.S. government. Customs brokers do not take ownership or physical possession of organic products and their actions present minimal risk to organic integrity. They are often distinct from sales or commodity brokers, who sell or facilitate the sale of organic products—those operations must be certified if they handle organic products. Customs brokers also play a critical role by filing NOP Import Certificate data in the U.S. Customs and Border Protection's (CBP) Automated Commercial Environment (ACE) import entry system.

This exemption is limited to Customs brokers as defined by 19 CFR 111.1: “a person who is licensed under this part to transact customs business on behalf of others.”

Customs business is further defined in 19 CFR 111.1 and includes “activities involving transactions with CBP [U.S. Customs and Border Protection] concerning the entry and admissibility of merchandise...payment of duties, taxes, or other charges...the preparation...of documents in any format and the electronic transmission of documents...intended to be filed with CBP in furtherance of any other customs business activity...”¹⁷

To qualify for this exemption, Customs brokers must only conduct customs business. If a Customs broker conducts any additional activity within the definition of *handle*—such as selling, importing, or trading—the Customs broker must be certified.

Logistics brokers

Section 205.101(h) exempts from certification operations that only arrange for the shipping, storing, transport, or movement of organic agricultural products. Sometimes known as “logistics brokers,” these operations facilitate the movement and storage of agricultural products by connecting a consigner (or consignee) with a carrier who can transport/store the products. Logistics brokers do not take ownership or physical possession of organic products. The activities they conduct present minimal risk to organic integrity because they only secure transport/storage to meet the needs of a third party who owns or is responsible for the agricultural product.

This exemption is limited to operations that only arrange for the shipping, storing, transport, or movement of agricultural products and do not conduct any other activity in

¹⁷ See 19 CFR 111.1 for complete definitions of Customs broker and Customs business:
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=ab6e30d35ef538ce07bc8021d6e1d4c3&mc=true&n=sp19.1.111.a&r=SUBPART&ty=HTML#se19.1.111_11

the definition of *handle*. If such an operation conducts other handling activities—such as selling, importing, or trading—the operation must be certified.

Transport

Transport of agricultural products alone is not a handling activity and does not require certification (see definitions of *handle* in 7 CFR 205.2 and 7 U.S.C. 2502(8)).

Transport generally refers to the movement of products in commerce. Examples of activities which are transportation and do not require certification include: moving organic hay or milk from a certified producer to a certified organic buyer or certified processing facility, moving organic grain or organic livestock from certified organic farms to a certified handling or slaughter facility, and food delivery services transporting prepared foods from a retail establishment to a consumer.

Any activities other than the movement of product on a transportation vehicle or moving products between transportation vehicles (transloading) are handling and require certification. Handling activities which are adjacent to transport require certification unless they are covered by exemptions 205.101(e) or (f) for packaged products.

Examples of adjacent activities which do not qualify as transport include combining, splitting, containerizing, packing/repacking, treating, sorting, opening, enclosing, or labeling/relabeling. In addition, loading or unloading of unpackaged products into or from a storage facility is not a form of transportation; this activity must be certified.

Certified operations are responsible for verifying that products handled by uncertified entities in their supply chain remain in compliance with the organic regulations. This includes verifying organic products transported by an uncertified transporter. A certified operation needs to describe procedures for verifying suppliers in the supply chain and the organic status of products received (§ 205.201(a)(3)). In addition, certified operations must maintain records back to last certified operation, which may encompass uncertified operations that fall between certified entities (§

205.103(b)(2)). The certified organic operation responsible for the organic products that are transported must: maintain records, for the audit trail and traceability, in sufficient detail as to be readily understood and audited; demonstrate prevention of commingling and contamination during transportation (§ 205.272); fully describe the transportation practices in the organic system plan; and ensure that the transportation records for organic products are available for inspection. Certified operations that load or receive products from uncertified transporters can verify prevention of contamination/contact with prohibited substances through, for example, affidavits or other documentation of vehicle clean out.

Summary of changes to the final rule

AMS made several revisions to the proposed regulatory text when writing this rulemaking. Changes to the rulemaking are discussed below. This is then followed by responses to specific themes from public comment.

- AMS revised the definition of *handle* to include additional examples of activities that require organic certification. AMS added these activities in response to public comments, which asked for additional clarity about who must be certified. The additional activities in the definition more clearly indicate activities that require certification and will help businesses determine whether they need organic certification.
- AMS simplified the term *handler* and removed “except for operations that are exempt from certification” and “or a portion of [an operation]” from *handling operation*. These phrases are redundant because they are explained in § 205.100—What has to be certified. AMS also added “except final retailers of agricultural products that do not process agricultural products” to both definitions. This clarifies that certain final retailers are not handlers or handling operations

and aligns the definitions with OFPA. The two definitions are now mostly synonymous, differing only in their reference to either a person or an operation.

- The proposed rule would have replaced the defined term *retail food establishment* with the updated term *retail operation*, which focused on the key activities of retailers, notably those selling “directly to final consumers.” Many public comments noted that the proposed phrase “direct to final consumers” was imprecise and would not be interpreted consistently by stakeholders. These comments also indicated that stakeholders are familiar with the meaning of the original defined term *retail food establishment* and how to apply it. Therefore, this final rule uses the defined term *retail establishment*, which has language very similar to the original *retail food establishment*, to ensure consistent stakeholder understanding. This final defined term removes the word “food” because retailers sometimes sell non-food items; it also avoids the potentially confusing phrase “directly to final consumers.” Finally, this definition for *retail establishment* adds more examples of types of retail establishments to help stakeholders determine whether they are a retail establishment.
- AMS removed “or a portion of an operation” from the descriptions of each exemption; this language was redundant because it is included in § 205.100—What has to be certified.
- AMS removed references to § 205.272 because they are redundant to the reference to subpart C in the introductory paragraph of § 205.101.
- In the introductory paragraph of § 205.101, AMS replaced references to § 205.310 with a reference to subpart D. This more broadly references the labeling requirements exempt operations must follow, including use of the USDA seal and labeling in retail environments.

- In § 205.101(b), AMS removed “sells” to clarify that retail establishments may also perform some handling (not just selling) in the regular course of business.
- In § 205.101(c), AMS removed the reference to agricultural products “previously labeled for retail sale” and replaced it with the statement “certified under this part” to clarify that retailers may process certified organic products regardless of whether the products are labeled for retail sale or for other use (e.g., organic products labeled for food service).
- AMS revised §205.101(e) to exempt only storage of products sealed in tamper-evident packaging. Storage of unpackaged organic products is a high-risk activity that requires certification to maintain integrity. Sealed, tamper-evident packaging makes organic products less susceptible to fraud and mishandling and helps maintain organic integrity during storage and handling by uncertified operations.
- AMS added new paragraph (f) in § 205.101 to exempt the sale of retail products sealed in tamper-evident packaging. Sale of this type of packaged retail products presents little risk to organic integrity, and operations storing and selling these products do not require organic certification.
- AMS added new paragraphs (g) and (h) to § 205.101 to exempt Customs brokers and logistics brokers because these operations only facilitate entry of imports into the United States, and their activities do not present a risk to organic integrity.
- AMS removed recordkeeping requirements from specific exemptions and replaced them with a general “Recordkeeping by exempt operations” paragraph at § 205.101(i).
- AMS revised § 205.310 to remove “or excluded” and replaced “handled” with “processed” to more clearly indicate that products processed by an exempt operation must not be used as an ingredient in an organic product processed by others.

Summary of public comment

AMS received many public comments from stakeholders across the organic industry discussing this section of the proposed rule. The majority of comments generally supported AMS's proposed revisions and agreed that the organic regulations must clearly indicate who needs to be certified and reduce the types of uncertified operations in organic supply chain. Many commenters requested further clarification of the proposed changes, particularly about the need for organic certification and exemptions from certification.

Revised definitions

The revised definition of *handle* was discussed in many comments. Some commenters requested expanding the definition to include terms such as “port,” “transload,” and “brand owner” to the regulatory text. Commenters also requested specific distinctions be made between “transport” and “transload,” noting current inconsistency in how these are interpreted by the industry.

Some comments discussed further clarification needed, including how “cold storage” fits into the rule. Other comments requested to further clarify *handle* by better defining “split.” Another commenter requested clarification for operations that repackage or repurpose certified organic products for on-site sale (e.g., delis). A few commenters also requested AMS discuss virtual transactions more clearly.

In response to AMS's request for additional activities that may need to be certified, commenters suggested the following be added to the definition of *handle*: split, open, close, sort, combine, consolidate, aggregate, enclose, condition, treat, size, grade, transload, brand ownership, private label, import, export, commingle, transport, and deliver.

Exemptions

Certification of and exemption for brokers was frequently discussed in comments. Many commenters requested that brokering activities be exempt, with some requesting broad exemptions for all brokers and others favoring exemptions for certain brokering activities. These comments explained that exemptions are warranted because brokers typically do not take physical possession of the products. Many commenters also stated that all brokering activity should be certified, regardless of physical or financial possession.

Several comments requested changes or clarifications to the exemption for operations with organic sales of less than \$5,000, although the proposed rule did not revise existing policy. Most of these comments wrote in support of this exemption, though some proposed changes such as raising the maximum receipts to \$10,000 while still maintaining exempt status.

In general, some comments requested fewer exemptions, and asked AMS to implement a transition period for operations that would require certification under the rulemaking. Further comments wrote that operations that sell direct to consumers should be eligible for exemption. Several comments requested that storage facilities which only receive product packaged by a certified operation be exempt. One comment requested that products, not operations, be eligible for exemption because operations can interact with organic and non-organic products.

Some comments also requested clarification about private label brands. There was no clear consensus among comments about the need to certify such operations. Many comments stated that these operations must be certified, and that doing so would improve traceability and integrity. Others requested that private labels be exempt to avoid additional costs and labeling inconsistencies. Further comments requested that “private

label” be added to the definition of “retail establishment” because retail brands often sell private-labeled product.

Comments disagreed about the specific requirements exempt operations must follow. Some comments argued for more specific regulatory requirements for exempt operations (i.e., clarify what exempt operations can and cannot do). Many comments discussed the use of the USDA organic label by exempt operations, stating that exempt operations should not be permitted to use the certified organic label. They requested that whenever the organic label is used, the business must be certified.

Transport

Many comments requested specific exemptions for most transportation of organic products. Specifically, several comments requested that milk hauling and transportation between two certified operations should be exempt from certification. While the majority of comments requested these types of transportation be exempt, some comments disagreed, requesting limits on transportation exemptions. Other comments requested clarification for whether third-party delivery services that restaurants use are exempt. Finally, some comments also asked AMS to clarify whether transloading activities need to be certified.

Recordkeeping and compliance

Some comments were concerned with verifying exempt operations compliance. Several commenters suggested requiring universal use of affidavits when doing business with exempt operations. Another suggested utilizing invoices to track compliance using mass-balance audits.

Many comments addressed recordkeeping. Several comments requested modifying recordkeeping requirements to require exempt operations to maintain records for five years to align requirements for certified and exempt operations. Other comments wrote

that the recordkeeping requirements are burdensome for exempt businesses and asked AMS to not require certain recordkeeping practices.

Responses to public comment

Definition of handle

(Comment) AMS received many comments about the definition of *handle* and activities that should or should not require certification. Comments discussed a wide range of activities spanning all segments of the supply chain and suggested many additional activities to include in the definition of *handle*, including to split, open, close, sort, combine, consolidate, aggregate, enclose, condition, treat, size, grade, transload, brand ownership, private label, import, export, commingle, transport, and deliver. Conversely, comments also provided examples of activities that should not require certification, including storing packaged products, transporting, delivering, repackaging or splitting cases of retail-packaged products, loading, receiving, brokering, selling or trading packaged products, selling retail products, or labeling for inventory purposes.

(Response) AMS agrees that some of the activities presented by commenters require certification and has added more examples to the definition of *handle* to help clarify who and what activities must be certified. The definition of *handle* is not an exhaustive list of activities that must be certified. There may be additional activities not listed in the definition that require certification, or different words or synonyms for the same or similar activities. The absence of a specific term in the definition of *handle* does not mean the activity is not handling or that an operation conducting this activity does not need certification. More specific responses to certain activities are discussed below.

(Comment) Several comments noted the difference between the definitions of *handler* and *handling operation* and asked AMS to either clarify this difference, or harmonize the two definitions.

(Response) AMS simplified *handler* and removed “except for operations that are exempt from certification” and “or a portion of [an operation]” from *handling operation*. These phrases are redundant because they are explained in § 205.100—What has to be certified. AMS also added “except final retailers of agricultural products that do not process agricultural products” to both definitions. This clarifies that certain final retailers are not handlers or handling operations, and aligns the definitions with OFPA. The two definitions are now mostly synonymous, differing only in their reference to either a person or an operation.

(Comment) Several comments asked AMS to include importing and exporting to the definition of *handle*, noting that the mandatory use of NOP Import Certificates requires certification of importers and exporters.

(Response) AMS agrees with these comments and has added importing to the United States and exporting for sale in the United States to the definition to help clarify that these activities require certification, and to support the mandatory use of NOP Import Certificates described in Section 2 of this rule, Imports to the United States.

(Comment) Commenters questioned the inclusion of “facilitating sale or trade” in the definition for *handle*. The comments explained that the meaning is vague and too broad and would result in customs brokers, freight forwarders, sales brokers, and administrative activities requiring certification.

(Response) The original definition for *handle* covered many activities in the supply chain, from post-production to retail sale. The updated definition is specific about which activities are included in “sell, process or package.” However, the list of activities is not exhaustive and does not capture all activities that may be considered as selling, processing, or packaging an agricultural product. AMS included “facilitating sale or trade on behalf of a seller or oneself” as a general category to capture activities which are integral to selling a product and may be known by various names. The definition for

handle includes handling activities that fall under AMS’s authority, although sometimes certain activities listed in *handle* may not require certification. For example, entities that perform lower risk activities—such as Customs brokers, logistics providers (e.g., freight forwarders), and limited handling of packaged products—may be exempt from certification (see § 205.101(e) – (h)).

Retail

(Comment) AMS received comments requesting clarification regarding whether distribution centers and transport vehicles associated with a retail establishment are exempt from certification. Some commenters requested that off-site warehouses and distribution centers not be exempt unless they meet proposed § 205.101(e). According to commenters, this clarification is needed to ensure that distribution centers do not avoid certification by claiming to be an exempt retail establishment.

(Response) A warehouse or distribution center associated with a retail establishment is only exempt if it meets the criteria described in § 205.101(e) or (f). Transport vehicles associated with a retail establishment do not require certification if they only transport and do not handle organic agricultural products per § 205.2.

(Comment) AMS received comments asking whether virtual transactions with a final consumer are exempt from certification. Although a few comments asked NOP to either exempt or require certification of this activity, most comments did not give an opinion and only asked NOP for clarification.

(Response) AMS has provided additional clarification by noting that only businesses that meet the definition for *retail establishment* are exempt under § 205.101(b) and (c). Virtual businesses that only sell retail packaged products to consumers, but do not qualify as retail establishments, may be exempt from certification if they meet the criteria of § 205.101(f). AMS provides further detail in the “Retail establishments” section of the preamble.

(Comment) Comments noted that the proposed definition of *retail operation* did not include the list of examples that was provided in the preamble, and asked AMS to add them to the definition.

(Response) AMS agrees that the examples help clarify the definition and has added them to the final definition of *retail establishment*.

(Comment) Comments requested revising the exemption for retailers that process by not limiting this to processing only products that were previously labeled for retail sale.

Comments indicated that retailers commonly source products labeled for food service.

(Response) AMS has removed that qualification from § 205.101(c) to clarify that exempt retail establishments may process certified organic products regardless of whether the products are labeled for retail sale.

(Comment) AMS received comments asking about the status of food delivery services, specifically those affiliated with or serving retail operations. Although a few comments asked NOP to either exempt or require certification of this activity, most comments did not give an opinion and only asked NOP for clarification.

(Response) Services which deliver products from a retail establishment to a consumer may not require certification. A service which delivers product from the retailer to the consumer after final sale and does not engage in handling is transport and does not require certification.

(Comment) Comments requested clearer guidance on what handling activities retail operations could engage in and remain exempt. Comments explained that the exemption for retailers that only sell and retailers that process creates uncertainty for the many retail operations that sell and handle. A few comments gave specific examples of activities that exempt retail establishments should be allowed to conduct, including removing/unpacking products, washing and transferring products to retail displays, and

breaking down master cases of individual packaged products. However, most comments did not give an opinion and only asked NOP for clarification.

(Response) AMS has revised the definitions of *handler* and *handling operation* to exclude retailers that do not process organic agricultural products; these operations may not require certification. This is reinforced by the exemption for retailers that handle but do not process at § 205.101(b), which acknowledges that exempt retail establishments may perform some handling activities. AMS has also revised the definition for *handle* to be more specific about the types of activities included. The additional description will help to clarify the differences and overlap in handling and processing activities.

(Comment) Comments asked to clarify the meaning of “point of sale” in reference to virtual transactions for retailers. There was a suggestion to allow virtual transactions only when the sale occurs from a brick-and-mortar retail location, to prohibit retailers that sell only via an online platform.

(Response) The definition for retail establishment allows for virtual retail transactions. For a retail establishment to be exempt, the sales must occur at the same location as the processing, and there must also be a physical location for consumers to purchase products.

Storage

(Comment) AMS received comments stating that storage of unpackaged or bulk organic products is high-risk and should require certification. They also noted that the proposed rule eliminated the distinction between packaged and unpackaged product relating to receiving, storing, and loading activities; this could allow high-risk operations such as grain elevators and ports of entry to be exempt from certification. Some comments requested AMS only exempt the storage of sealed, tamper-evident packaged products.

(Response) AMS has revised the exemption at § 205.101(e) to exempt only operations that store, receive, and prepare for shipment organic products in sealed, tamper-evident

packages. Products must remain in their packages and the exempt operation must not handle the product beyond storing, loading, and preparing for shipment. Operations that store bulk products or products not packaged in sealed, tamper-evident packaging must be certified.

AMS made this change because the proposed rule would have exempted operations that store unpackaged or bulk organic products. Many public comments noted that storage of unpackaged organic products is a high-risk activity that requires certification to maintain integrity. AMS agrees that storage of unpackaged products is a high-risk activity. Lack of sealed or protective packaging increases the likelihood of contamination with prohibited materials (e.g., pesticides and fumigants), commingling with nonorganic products, and misidentification. These risks are especially great in high-activity areas, and storage of unpackaged products requires additional care and oversight to ensure organic integrity is maintained. Therefore, AMS is requiring certification of operations that store unpackaged products. Conversely, because packaging reduces the risk of contamination, commingling, and misidentification, AMS is granting an exemption from certification for operations that only store packaged products that are sealed upon arrival and remain in their packaging.

AMS has narrowed the exemption to include only operations that store, receive, and/or prepare for shipment organic products in sealed, tamper-evident packaging. Sealed, tamper-evident packaging makes organic products less susceptible to fraud and mishandling and helps maintain organic integrity during storage and handling by uncertified operations.

(Comment) Commenters requested AMS exempt from certification activities where packaged product remains in its container, such as breaking up pallets of packaged organic products that remain in its original inner packaging, or placing such products into a retail display.

(Response) Section 205.101(e) and (f) exempt operations that receive, store, and prepare for shipment organic products enclosed in sealed, tamper-evident packages or containers. Preparing for shipment may include various tasks that must be performed with the sealed, tamper-evident packaging remaining intact and without altering product contents or any retail labeling. Examples of preparing for shipment include putting packaged products into shipping containers, applying internal tracking numbers, shrink-wrapping shipping cartons to a pallet, breaking down pallets of fully packaged products, adding protective packaging to nonretail containers or retail displays of organic products, packing individual packaged products onto a shipping pallet, placing individual retail packages into a retail display, and loading/unloading packaged products onto or from transport vehicles.

(Comment) Several comments asked if cold storage of organic agricultural products is exempt from certification, pointing to the inclusion of “chilling” in the definition of *processing*.

(Response) Cold storage of organic agricultural products may be exempt from organic certification if the activity meets the criteria of § 205.101(e), i.e., only sealed, tamper-proof packaged organic products are stored. The act of cooling packaged organic products is a common low-risk storage activity that is different from “chilling” performed as part of organic product processing.

(Comment) Several commenters requested that AMS remove the verb “loads” from proposed § 205.101(e) for operations that storage organic products, arguing that “load” could be conflated with handling activities such as placing or packaging bulk products into containers.

(Response) AMS uses “prepare for shipment” in exemptions at § 205.101(e)–(f) to clarify that these exempt operations may not perform activities such as packaging or loading bulk products into containers. Prepare for shipment means that these operations

may move products into or onto a mode of transport, provided that the products are packaged per § 205.101(e)–(f).

(Comment) One commenter asked AMS to require certification of storage facilities that store both organic and nonorganic agricultural products. They argue that such “split” storage operations are a known source of contamination and commingling, and that certification is necessary to prevent this.

(Response) This rulemaking addresses the risks of contamination and commingling by split storage operations by (1) requiring the certification of operations that handle unpackaged organic products and (2) limiting the exemption for storage operations to only those that handle sealed, tamper-proof packaged organic products. AMS believes these changes will mitigate the risks of split operations.

Additionally, § 205.100(a) states that “each operation *or portion of an operation*” that handles organic agricultural products must be certified. Similarly, the exemption at § 205.101(e), which allows storage of packaged organic products without certification, would be limited to only the portions of an operation that meet the narrow criteria of this exemption. This means that a portion of a split operation that stores unpackaged organic products needs to be certified.

Transport

(Comment) Commenters requested that AMS explicitly state what transportation activities are exempt from certification. They also noted that the regulatory text and preamble lack a specific exemption for transport of agricultural products.

(Response) The OFPA provides AMS authority to regulate the handling (i.e., selling, processing, or packaging) of organic agricultural products; however, transportation activities are not included in this authority. Transport is generally described as the movement of products in commerce. Based on the OFPA, transport of organic agricultural products does not need to be certified; however, any handling activities that

occur during transport must be. See the definition of *handle* for examples of activities that may require certification.

(Comment) AMS received several comments asking if milk haulers will require organic certification. Most comments requested only clarification on this topic, but several specifically requested that milk haulers be exempted from certification.

(Response) AMS is defining the need for certification based on activities performed, not type of business, because this will ensure that businesses conducting high-risk activities require certification (and conversely that businesses that conduct low-risk activities remain exempt). A milk hauler would be exempt from certification if they *only* transport organic milk (e.g., move milk from a dairy to a processor) but do not otherwise handle the milk (e.g., process or package loads of milk). Transport alone does not require certification.

(Comment) AMS received comments requesting that the transport exemption be limited to transport from one certified operator to another, or to a final retailer, to ensure traceability of product throughout supply chains.

(Response) AMS is not restricting transport of organic agricultural products from one certified operation to another. This rule ensures traceability via other means: certified operations must maintain audit trail documentation for products they produce or handle (§ 205.103(b)(3)) and keep records to trace organic products received back to the last certified operation in the supply chain (§ 205.103(b)(2)). This means that certified operations must ensure traceability of products transported by uncertified operations, including if several uncertified transporters are used in sequence.

(Comment) Many comments discussed transloading organic agricultural products and asked AMS to clarify if this activity requires certification.

(Response) Transloading is commonly defined as the movement of agricultural products between modes of transport. AMS does not have the authority to regulate transport.

Therefore, transloading strictly between modes of transportation does not need to be certified.

However, transloading is sometimes used to describe the movement of agricultural products from storage to transport or transport to storage. AMS considers these activities to be loading and receiving (see § 205.2 and the definition of *handle*). Moving unpackaged organic agricultural products from storage to transport, or from transport to storage, requires certification. If the organic agricultural products are enclosed in sealed, tamper-proof containers or packages, then loading and receiving is exempt from certification.

Small operations

(Comment) Several comments discussed the exemption for small operations at § 205.101(a). A few commenters asked AMS to clarify if the exemption applies to both production and handling operations. Others requested that AMS allow ingredients produced or processed by such exempt operations to be used as certified organic ingredients produced by other operations. One commenter requested AMS increase the gross sales limit of \$5,000.

(Response) This rulemaking does not modify current policy regarding the exemption for small operations. Section 205.101(a) exempts operations that produce *or handle* agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually. However, these operations must not sell, label, or represent agricultural products they produce or process as *certified* organic, and such products must not be used as certified organic ingredients in products processed by another operation (see § 205.310). Additionally, the \$5,000 gross sales threshold is set by the OFPA, and AMS does not have authority to increase this limit.

Selling and representing

(Comment) Many comments requested that AMS provide exemptions for operations that do not physically handle or contact organic agricultural products, arguing that such operations do not threaten organic integrity.

(Response) AMS disagrees with commenters' claim that lack of physical contact equals low risk. Organic integrity depends on oversight and transparency across the entire organic supply chain—including some operations that may never physically contact organic products. The need for certification is based on risk and this rule requires certification of high-risk operations such as importers, traders, and others that facilitate the sale of organic products. Although these operations may not physically contact organic products, they control critical events along organic supply chains where organic integrity can be compromised, including purchase, sale, transport, storage, and combining or splitting products. For example, an importer, broker, or trader could unintentionally compromise the integrity of organic products they buy or sell by not seeking or keeping records to demonstrate traceability and verify organic integrity. Without these records, there is no way to verify that a product was properly handled by the multiple physical handlers in a supply chain. A breach of integrity could go unreported, and the importer or trader would unintentionally sell a product that has lost its organic status and integrity. Similarly, brokers and traders could mistakenly direct contracted storage facilities and transporters to perform activities that compromise organic integrity, such as directing a storage facility to fumigate a container of organic wheat or directing a transporter to combine loads of organic and nonorganic corn.

Additionally, because importers, brokers, traders and others that facilitate sales have direct financial interest in the transaction of organic products, they have the incentive and opportunity to commit fraud. For example, an operation could falsify records to claim that a nonorganic product is certified organic, or direct a contracted storage facility or

transporter to mix organic and nonorganic products, and then claim the entire load is organic. NOP has investigated many notable cases of fraud committed by uncertified operations that did not physically contact the products in question (see the discussion on fraud under “Purpose and Need for the Rule”).

The risk of both unintentional breach of integrity and fraud has grown with the organic market as supply chains increase in complexity and more uncertified parties affect control of organic products and their transaction. Requiring certification based on risk ensures traceability, verification, accountability, and oversight at the most critical points of the supply chain, including the activities of brokers, traders, importers, and others who facilitate sale but may not physically contact organic products. The rule also provides reasonable exemptions for low-risk operations to reduce cost and administrative burden to the industry.

(Comment) Many comments discussed private labeling and brand ownership of organic products. Opinions differed about the need to certify these operations. Some commenters argued that requiring certification of these operations would improve transparency and traceability of products, while others claimed that doing so would be unnecessary and create potential problems with labeling and traceability.

(Response) “Brand owners” or operations that sell or distribute organic products produced by another operation on their behalf may be exempt from certification if they meet the criteria of § 205.101(f). This exemption allows the buying, selling, receiving, storing, and preparing for shipment of organic products that are packaged for retail sale. The products must be sealed in tamper-evident packaging ready for retail sale, and the operation must not open or otherwise handle the retail packages. Private labeling operations that process organic agricultural products must be certified.

(Comment) Commenters asked AMS to clarify if sales brokers need to be certified, including businesses that buy or sell only packaged organic products.

(Response) Operations that sell, trade, or facilitate sale or trade of organic agricultural products on behalf of a seller or oneself must be certified. However, AMS is providing an exemption for operations that only buy, sell, receive, store, or prepare for shipment organic products packaged for retail sale (§ 205.101(f)). The products must be sealed in tamper-evident packaging labeled for retail sale, and the operation must not open or otherwise handle the retail packages. Sale of organic products not packaged for retail sale (e.g., bulk; unpackaged; packaged for nonretail sale; unsealed, non-tamper-evident packaging) must be certified.

Supply chain logistics

(Comment) Many comments asked AMS to provide a specific exemption for Customs brokers licensed by U.S. Customs and Border Protection, arguing that these operations only facilitate entry of imports into the United States, and that their activities do not present a risk to organic integrity.

(Response) AMS agrees that the activities of Customs brokers do not threaten organic integrity. Therefore, § 205.101(g) exempts from certification licensed Customs brokers that only conduct Customs business per 19 CFR 111.1. This exemption is limited to Customs business; other activities conducted by a Customs broker that fall within the definition of *handle*—including selling, importing, or trading organic agricultural products—may require certification.

(Comment) Several comments asked AMS to clarify if businesses that facilitate the storage and transport of organic agricultural products, such as logistics brokers and freight forwarders, require certification.

(Response) Logistics brokers, freight forwarders, and other businesses that facilitate storage and transport of agricultural products may be exempt if they meet the criteria of §§ 205.101(e) or (h). These exemptions only apply to operations that conduct or facilitate specific shipping, storing, or transport activities. This may include logistics

brokers or freight forwarders who do not take ownership or physical possession of organic products and only provide a service by connecting a consigner (or consignee) with a carrier who transports/stores the products. Additionally, transport of organic agricultural products does not require certification if the transport operation does not handle the products (see definition of *handle* in § 205.2). Other handling activities—such as selling, importing, or trading—must be certified.

(Comment) Many commenters responded to AMS’s request for comment about ports of entry. Most commenters agreed that the activities of ports—such as loading, storing, receiving, combining, and splitting—must be certified if unpackaged products are being handled. Comments stated that handling of unpackaged goods at ports should be certified because ports conduct physical activities that can compromise organic integrity. Ports unload, move, split, combine, and store both organic and nonorganic products, increasing the risk of commingling organic and nonorganic products, and the risk of contamination with substances not allowed in organic handling. In contrast, several comments from trade associations state that requiring certification of port activities may cause delays, increase costs, and may have limited positive impacts on organic integrity. Several comments asked AMS for more clarification about the need for ports of entry to be certified.

(Response) Ports of entry must be certified if the activities they conduct meet the definition of *handle* and do not clearly fit an exemption at § 205.101(a)–(h).

Recordkeeping and verification

(Comment) Several comments noted that proposed § 205.101 did not clearly explain the requirements and recordkeeping practices each exempt operation must follow. A few comments also asked AMS to increase the recordkeeping requirement for exempt operations to five years to be consistent with requirements for certified operations.

(Response) AMS has revised § 205.101 to clarify the requirements and recordkeeping practices that exempt operations must follow. Specific references to individual requirements are removed from each exemption, and the introductory paragraph explains universally that all exempt operations must follow the applicable production, handling, and labeling requirements of subparts C and D. The preamble further explains with specific examples of requirements exempt operations may have to follow.

AMS has also removed recordkeeping requirements from individual exemptions and replaced them with a single, consistent recordkeeping requirement that applies universally to most exempt operations. AMS retained the requirements for exempt operations to maintain records for at least three years because there was not a compelling reason for increasing that timeframe without prior notice.

(Comment) AMS received several comments asking who is responsible for verifying exempt operations' compliance with the organic regulations.

(Response) Certified operations are responsible for verifying the compliance of the certified organic products they receive, including those received from exempt operations. Section 205.201(a)(3) requires a certified operation's OSP to include monitoring practices and procedures to verify suppliers (including exempt suppliers) and the organic status of products they receive. AMS is not prescribing how certified operations should verify suppliers and products; this provides flexibility for operations to develop and implement practices that best suit their business and the products they handle.

B. Imports to the United States.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.2	Terms Defined. Definitions for <i>Organic exporter</i> and <i>Organic importer</i> .
205.273	Imports to the United States. Entire section.

205.300	Use of the term, “organic.” Paragraph (c).
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Purpose, scope, and authority

AMS is amending the USDA organic regulations by adding a new section (205.273) requiring the use of the National Organic Program Import Certificate (“NOP Import Certificate”). The NOP Import Certificate is a transaction certificate, or data set, that contains detailed information about the quantity and origin of organic product being imported into the United States. Any organic agricultural product imported to the United States must be associated with a valid NOP Import Certificate, generated by the certifying agent of the final certified exporter sending the product to the United States.

The purpose of the NOP Import Certificate is to document the organic status and quantity of imported organic products as they travel from a certified organic exporter in a foreign country to a certified organic importer in the United States. The NOP Import Certificate ensures an auditable business transaction by documenting that the products in the shipment are organic and may be sold, represented, and distributed as organic within the United States.

The mandatory use of NOP Import Certificates is authorized by the Organic Foods Production Act (OFPA), as amended by the “2018 Farm Bill”.¹⁸ The OFPA specifies what information an NOP Import Certificate must include (7 U.S.C. 6502(13)) and also stipulates that the NOP Import Certificate must “be available as an electronic record” and captured in a tracking system maintained by the U.S. Government (7 U.S.C. 6514(d)). The OFPA also provides the Secretary with broad authority to establish appropriate and adequate enforcement procedures and any other requirements that the Secretary may determine to be necessary (7 U.S.C. 6506).

¹⁸ See sections 10104(b)(3) and 10104(c) of the Agriculture Improvement Act of 2018, Pub. L. 115-334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

The NOP Import Certificate must be presented to U.S. Customs and Border Protection (CBP) through the CBP Automated Commercial Environment (ACE). The use of this standardized electronic format will ensure consistency in data for auditing, surveillance, and enforcement purposes. The OFPA, as amended by the 2018 Farm Bill, states that AMS must establish a system of tracking NOP Import Certificates, and that AMS “may integrate the system into any existing information tracking systems for imports of agricultural products” (7 U.S.C. 6514(d) and 6522(c)).¹⁹

Because the OFPA enables AMS to access information available in ACE (7 U.S.C. 6521(c)), AMS is using ACE to accept NOP Import Certificate data.²⁰ ACE is an automated and electronic system for processing commercial trade data. It is the primary system through which the global trade community files information about imports and exports so that admissibility into the United States may be determined by government agencies (including AMS) to ensure compliance.

The data to be entered into ACE include fields for the information needed to meet the requirements of an NOP Import Certificate as defined in the OFPA: origin; destination; the certifying agent issuing the NOP Import Certificate; harmonized tariff code, when applicable; total weight; and the organic standard the product was certified to (7 U.S.C. 6502(13)). For the purposes of uploading and tracking NOP Import Certificates, the data must be available as an electronic format to meet the requirements of the OFPA (7 U.S.C. 6514(d)(1)).

Both the OFPA and the USDA organic regulations require certified operations to maintain and make available to the Secretary records that concern the production, harvesting, and handling of agricultural products that are or that are intended to be sold,

¹⁹ See section 10104(c) of the Agriculture Improvement Act of 2018, Pub. L. 115-334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

²⁰ See sections 10104(h) and (j) of the Agriculture Improvement Act of 2018, Pub. L. 115-334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

labeled, or represented as organic. This includes sufficient records to provide an audit trail to determine the source, type and quantity, transfer of ownership, and transportation of any agricultural product labeled as organic. Likewise, both the OFPA and the USDA organic regulations require certifying agents to maintain and make available to the Secretary records concerning its activities.

This policy also aligns with international guidelines and norms related to organic oversight. NOP considered international standards established by the Codex Alimentarius Commission (Codex)²¹ and norms published by the International Federation of Organic Agriculture Movements (IFOAM).²² Both provide for and support the use of transaction shipment certificates such as the NOP Import Certificate.

Change from current policy

NOP Import Certificates are currently only used for organic products imported from countries with which AMS has an equivalence determination. The USDA has established equivalence determinations with Canada, the European Union, Switzerland, Japan, South Korea, Taiwan, and the United Kingdom. Organic imports from Canada are accompanied by an organic certificate that includes an attestation statement that the products comply with the terms of the United States-Canada Organic Equivalency Arrangement. Organic imports from the European Union, Switzerland, Japan, South Korea, Taiwan, and the United Kingdom are accompanied by an NOP Import Certificate. The certifying agent of the exporter evaluates the request for an NOP Import Certificate, and upon verification of the organic shipment, completes and issues an NOP Import Certificate. Form NOP 2110-1 is currently used for this purpose.

²¹ Section 7 of the *Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* recommends imported organic products to be marketed only where the competent authority or designated body in the exporting country has issued a certificate of inspection stating that the lot designated in the certificate was obtained within an organic system of production, preparation, marketing, and inspection.

²² IFOAM Norms define a transaction certificate as a “document issued by a certification body or by the operator, declaring that a specified lot or consignment of goods is certified.”

In the past, AMS has not required NOP Import Certificates for organic exports from countries with which the United States does not have an organic equivalence determination. The rulemaking changes this to make the use of NOP Import Certificates mandatory, regardless of an imported product's country of origin or if that country has an equivalency determination with USDA. Specifically, this rulemaking requires that all imported products intended to be sold, represented, labeled, or marketed as organic in the United States must be declared as organic to U.S. Customs and Border Protection (CBP), using an NOP Import Certificate.

Alignment of policy with U.S. Customs and Border Protection policies and systems

The OFPA, as amended by the 2018 Farm Bill, requires the establishment of an Organic Agricultural Product Imports Interagency Working Group, consisting of members of both the USDA and CBP (see 7 U.S.C. 6521a).²³ The mandatory use of NOP Import Certificates supports the working group's goal to ensure the compliance of organic agricultural products imported into the United States.

Under this policy, AMS and CBP will collaborate to verify that imported organic products are associated with NOP Import Certificates. In April 2020, the electronic version of the NOP Import Certificate was deployed in ACE as an optional filing step for organic imports. The use of the electronic NOP Import Certificate will be mandatory once this rule is fully implemented.

NOP Import Certificates will be required for any commodity imported into the United States that is being manifested, sold, marketed, or labeled organic. NOP Import Certificates are required for organic commodities regardless of value or size and is not applicable for any de Minimis exemptions under current CBP regulations.

²³ See section 10104(i) of the Agriculture Improvement Act of 2018, Public Law No: 115-334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

Generating the NOP Import Certificate

This section describes how the NOP Import Certificate data are generated. NOP Import Certificates must be generated using the USDA's Organic Integrity Database. By the time the rule is fully implemented, both USDA-accredited certifying agents and organic certifying agents accredited by countries with which USDA holds an organic trade arrangement or agreement (equivalence determination or recognition arrangement) will have access to the Organic Integrity Database to generate NOP Import Certificates. Only the Organic Integrity Database can be used to generate valid NOP Import Certificates, and only accredited organic certifying agents (USDA or under an organic trade arrangement or agreement) are authorized to use the Organic Integrity Database.

Where does the data for the NOP Import Certificate come from?

The data for the NOP Import Certificate is generated in the Organic Integrity Database by the certifying agent of the exporter. The exporter is responsible for facilitating the trading, selling, consigning, shipping, or exporting of organic product from a foreign country to the United States. An organic exporter must be certified organic by certifying agents accredited by the USDA or certifying agents authorized by a trade arrangement or agreement. Organic exporters may be the final physical handler of organic products within a foreign country, or they may be the entities that facilitate, sell, or arrange the sale of organic products shipped to the United States.

This exporter is responsible for verifying that the organic product complies with organic standards. This includes, but is not limited to, verifying that the import has not been exposed to a prohibited substance, treated with a prohibited substance as a result of fumigation or treated with ionizing radiation at any point in the products' movements across country borders.

How does the certifying agent evaluate the request for an NOP Import Certificate?

The certifying agent determines the format of the NOP Import Certificate request from the certified operation, based on the data required for the Organic Integrity Database to generate the NOP Import Certificate. The request for an NOP Import Certificate must include all information required by the organic exporter's certifying agent to complete the NOP Import Certificate. The certifying agent is required to confirm the authenticity of the organic products covered by the NOP Import Certificate using control systems it designs for this purpose. The certifying agent must have and implement a documented organic control system for intaking and approving or rejecting the validity of an NOP Import Certificate request.

The certifying agent is responsible for ensuring that the issued NOP Import Certificate is only associated with an amount of product that has been verified to be certified organic. The certifying agent has the authority to determine whether it will issue an NOP Import Certificate for a specific shipment, or for a specific timeframe (e.g., weekly, monthly, season) and amount or volume ceiling. This determination is to be based on the capacity and control systems of both the certifying agent and the certified operation. There is no limit on the length of timeframe a certifying agent chooses. However, the certifying agent must choose a timeframe that is appropriate to their administrative capacity and documented control system and allows them to verify the integrity of the specific type and volume of import.

Once the certifying agent verifies the authenticity of the organic export, the certifying agent enters or uploads the information needed into the Organic Integrity Database. Each NOP Import Certificate must be associated with a certified organic operation listed in the database, identified by a 10-digit code. The Organic Integrity Database will generate a unique NOP Import Certificate that includes both the 10-digit identifier for the operation and a unique numerical identifier for the NOP Import

Certificate. The certifying agent will provide the NOP Import Certificate, or data set with the NOP Import Certificate number, back to the certified organic exporter requesting the NOP Import Certificate. The certifying agent can cancel or void a NOP Import Certificate in the Organic Integrity Database at any time.

Transmitting the NOP Import Certificate from exporter to importer

The certified organic exporter provides the NOP Import Certificate to the U.S. importer, who provides it to the specific entity responsible for entering import information into the ACE system. This is typically an importer or designated Customs broker. The NOP Import Certificate data can be sent either electronically or via paper. The U.S. importer or Customs broker enters the NOP Import Certificate data into ACE as part of its standard import filing process; this process is governed by timelines determined by CBP. Organic certifying agents will not have access to ACE; this activity is done by the importer or its Customs broker, using the NOP Import Certificate data provided by the certifying agent to the exporter.

As the certified organic product itself moves from the exporting country into the United States, all entry documentation including, but not limited to bills of lading, bills of sale, commercial invoices, and packing lists must clearly state that the product is organic. Exporting and importing operations must maintain records required under § 205.103. CBP may hold shipments at the border to address health and safety issues or violations of U.S. trade laws with a specific commodity or shipment.

Importer responsibilities

Upon receiving a shipment, an organic importer must verify that the organic product(s) comply with the USDA organic regulations. This includes ensuring that an NOP Import Certificate is associated with the product received. It also includes verifying that the import has not been treated with a prohibited substance as a result of fumigation or treated with ionizing radiation at any point in the products' movements across borders.

Verification may take many forms, depending on the documentation provided, and country and commodity. The importer must have an organic control system that documents how this verification is conducted to protect the organic integrity of imported product. This control system is reviewed by the importer's certifying agent.

Both the organic exporter and U.S. organic importer must maintain records of NOP Import Certificates, and these records must be available for inspection by the NOP and certifying agents in accordance with § 205.103. Certifying agents that are overseeing imports of organic products into the United States must have a system for ensuring that operations receiving organic product are receiving and maintaining NOP Import Certificates, and that they are not accepting more product from any providers than is authorized by NOP Import Certificates.

Connecting NOP Import Certificate with ACE import data

Once NOP Import Certificate Data is entered into ACE, the data are transmitted to AMS for analysis, surveillance, and enforcement. AMS will align and validate the data generated in ACE with the original NOP Import Certificate entered into the Organic Integrity Database. This will connect the data about the actual imported product back to the data about the corresponding authorized export, aligning both sides of the transaction. This alignment will allow for the identification of any anomalies or indicators of fraud, such as: NOP Import Certificates in ACE that were not authorized (do not have a valid certificate number) by a certifying agent in the Organic Integrity Database (e.g., fraudulent certificates); volumes of product entered in ACE that exceed those authorized in the Organic Integrity Database; and/or entries into ACE that are associated with an operation that is no longer certified. This type of automated data-driven surveillance is a common approach in trade oversight.

Timing of the NOP Import Certificate

The timing of the NOP Import Certificate data entry into ACE must comply with current CBP import filing requirements for Partner Government Agencies. The certified organic exporter must time the NOP Import Certificate request in such a way that the certifying agent has time to consider the request and generate the NOP Import Certificate, and the exporter has time to deliver it to the importer or Customs broker before the CBP filing requirements for the product.

Requiring an NOP Import Certificate provides trackable and auditable verification that organic products comply with the USDA organic regulations. This requirement will also support investigations if noncompliant products are exported and misrepresented as organic for sale in the United States. Given that the Organic Integrity Database will be the definitive tool for generating NOP Import Certificates, additional guidelines on data entry to generate NOP Import Certificates will be provided through that system.

Summary of changes to the final rule

AMS made several changes to the regulatory text of the SOE proposed rule when writing this final rule. Changes to the final rule are discussed below and are followed by responses to specific themes from public comment.

- AMS removed “owner” from the definition of *organic exporter*, added “certified” before “exporter,” and “to the United States” after “from a foreign country.” This clarifies that the organic exporter must be certified, and that the organic exporter may be the final physical handler of organic products within a foreign country, or they may be the entities that facilitate, sell, or arrange the sale of organic products shipped to the United States. This was done to clarify questions about “who needs to be certified” received during public comment.
- AMS removed “of record” from the definition of *organic importer* and added a statement that the organic importer is responsible for entering NOP Import

Certificate data into ACE. This addresses public commenters' request to clarify the role of the organic importer and the person responsible for entering data into ACE.

- AMS removed “through a U.S. Port of Entry,” as all imports must enter through such a Port, so the phrase is not needed.
- AMS removed references to “or equivalent data source” and “NOP Form 2110-1” throughout § 205.273 and clarified that the Organic Integrity Database must be used to issue NOP Import Certificates. AMS has determined that the Organic Integrity Database will be the only data source for NOP Import Certificates because it is a preexisting, proven tool that meets U.S. government security requirements, and already accepts data in multiple different forms to accommodate data inputs from other systems. The Organic Integrity Database is already used and understood by certifying agents, including many accredited by both the USDA and trade partner countries. It is a system that accepts data in multiple forms, that any government can engage with, and that minimizes onboarding time and learning curve. Using the Organic Integrity Database as a single source of certification and import data, while allowing multiple data upload methods, will provide secure access to import data that facilitates the use of NOP Import Certificates.
- AMS clarified that certifying agents may issue NOP Import Certificates for a specific timeframe, if appropriate, not limited to a single transaction. This addresses public commenters' concerns about generating NOP Import Certificates for multiple shipments in short timeframes (e.g., multiple shipments of fresh produce across the border). This change allows certifying agents to determine whether they will issue an NOP Import Certificate for a specific shipment or for a specific timeframe (e.g., weekly, monthly, seasonally) and amount or volume

ceiling. Because certifiers conduct certification activities on a one-year cycle, it is expected that import certificates are unlikely to exceed one year in duration. The certifying agent must choose a timeframe that is appropriate to their administrative capacity and documented control system, and allows them to verify the integrity of the specific type and volume of import.

- AMS clarified the requirement that certifying agents must have and implement a documented organic control system for intaking and approving or rejecting NOP Import Certificates. This ensures that certifying agents have auditable processes and procedures that NOP can audit to assess certifying agents' ability to generate and approve NOP Import Certificates.
- AMS removed the requirement that certifying agents must issue NOP Import Certificates within 30 days. This avoids any timing discrepancy between NOP Import Certificate data entry and CBP import filing requirements. AMS does not have authority to change CBP entry requirements. The timing of the NOP Import Certificate data entry into ACE must comply with current CBP import filing requirements for Partner Government Agencies.
- AMS clarified that organic importers must have a documented organic control system to verify NOP Import Certificates and verify no contact with prohibited substances or exposure to ionizing radiation. This is necessary to ensure that organic importers have auditable processes and procedures that certifying agents can review to assess importers' ability to verify NOP Import Certificates and verify the integrity of imported organic products.
- AMS clarified that organic importers must verify that the NOP Import Certificate data accurately reflects the shipment, which may include verification of quantities and types of product specified on the NOP Import Certificate. This requirement more clearly states the organic importer's responsibility in assessing and ensuring

the integrity of imported products, providing an additional layer of oversight at a critical juncture in organic supply chains.

Summary of public comment

The majority of public comments were strongly in support of AMS's proposed mandatory use of NOP Import Certificates. Many comments discussed or recommended changes to the NOP Import Certificate process, including the timing of NOP Import Certificates, ACE data entry, how the certificate should travel with the import, certifying agent role and capacity, and how the NOP Import Certificate would function within organic trade arrangements and agreements.

Comments frequently asked AMS to clarify if NOP Import Certificates can be issued before or after shipment. They also noted that the proposed 30-day requirement to issue NOP Import Certificates does not align with the 10-day ACE entry deadline noted in the preamble. Some comments requested that AMS allow up to 30 days to enter NOP Import Certificate data into ACE, while others recommended 10 days or less to help reduce fraud.

Many comments asked AMS to clarify if an NOP Import Certificate must “accompany” an import or be “associated with” an import. Several comments requested that AMS require imports be “accompanied” by an NOP Import Certificate and that the certificate travel with the import and be presented at entry into the United States, claiming that this would help prevent fraudulent organic products from entering the U.S. market. Others stated a preference to allow NOP Import Certificates to “be associated” with shipments, noting that this flexibility is needed to match the frequency and pace of land imports via truck and rail.

Several comments noted that issuing NOP Import Certificates for individual shipments would be difficult for high-volume, high-frequency imports, especially those from Canada and Mexico. These comments asked AMS to consider allowing certifying

agents to issue NOP Import Certificates that cover a specific time period (e.g., quarterly), product type, and volume. Comments argued this would reduce administrative burden and cost to both certified operations and certifying agents. A few comments also claimed that some certifying agents may not have the administrative capacity or technical expertise to issue and verify NOP Import Certificates as proposed.

A few comments asked AMS to clarify the definitions and roles of exporters and importers, noting that it is not clear who is responsible for requesting NOP Import Certificates, verifying them upon import, and entering data into ACE. Some comments also asked AMS to further define “equivalent data.”

Finally, some comments requested clarification about the general applicability and use of NOP Import Certificates, including their use for very small or infrequent shipments, use by exporters in a country AMS has a trade arrangement or agreement with, use of electronic vs. paper certificates, and use in trade between two foreign countries.

Responses to public comment

Timing of NOP Import Certificates

(Comment) AMS received many comments concerning the 30-day time frame for certifying agents to review and issue NOP Import Certificates. Commenters stated that the 30-day timeframe will negatively impact imports of perishable organic product from Canada and Mexico that require a rapid import process.

Other commenters stated that the 30-calendar-day timeframe for certifying agents to review and issue NOP Import Certificates does not align with the existing 10-day requirement to upload the NOP Import Certificate data into the ACE system. Others requested that the 10-day requirement for organic exporters to enter data from an NOP Import Certificates or equivalent into ACE align with the proposed 30-day requirement for certifying agents to issue an NOP Import Certificate or equivalent. Commenters also

requested that the 10-day timeframe to enter NOP Import Certificate data be reduced to prevent organic fraud.

More broadly, AMS received comments asking if NOP Import Certificates can be issued both before and after shipment. Additionally, commenters asked If NOP Import Certificates could be issued after the shipment of organic product has already entered the United States.

(Response) The timing of the NOP Import Certificate data entry into ACE must comply with current CBP import filing requirements for Partner Government Agencies. AMS does not have authority to change CBP entry requirements.

The certified organic exporter must time the NOP Import Certificate request in such a way that the certifying agent has time to consider the request and generate the NOP Import Certificate, and the exporter has time to deliver it to the importer or Customs broker before the CBP filing requirements for the product.

To address the problem of generating NOP Import Certificates for multiple shipments in short timeframes (e.g., multiple shipments of fresh produce across the border), AMS is granting the certifying agent the authority to determine whether it will issue an NOP Import Certificate for a specific shipment, or for a specific timeframe (e.g., weekly, monthly, season) and amount or volume ceiling. The certifying agent is responsible for ensuring that the issued NOP Import Certificate is only associated with an amount of product that has been verified to be certified organic.

Associated vs. accompanying

(Comment) Several commenters noted that proposed § 205.273(d) states that the organic importer of record must ensure that the shipment is *accompanied* by a verified NOP Import Certificate. This conflicts with the preamble which states that shipments of organic product must be *associated* with a valid NOP Import Certificate.

(Response) To clarify the requirement, AMS has removed the term *accompanied* from the rule. The NOP Import Certificate must be *associated* with a shipment. This revision accurately describes AMS's intent that organic shipments are associated with, and not accompanied by, a valid NOP Import Certificate at the time of entry into the United States.

(Comment) Commenters requested that the term *associated*, located in the preamble text, be changed to *accompany* and that AMS require NOP Import Certificates to be available upon entry to the United States, to prevent fraud in the organic market.

(Response) USDA is requiring that all organic exports to the United States be associated with a valid NOP Import Certificate. By requiring organic imports to be associated with, and not accompanied by, an NOP Import Certificate, USDA will have access to the import data without restricting or slowing import and trade of organic products.

Certifying agent capacity

(Comment) AMS received several comments highlighting that organic certifying agents lack the capacity to issue the number of NOP Import Certificates that would be required under the proposed rule at one per shipment. Comments specifically referenced the high-volume of organic products coming by truck and rail from Mexico and Canada.

(Response) It is the certifying agent's responsibility to ensure that the exporting operation has the capacity to produce or handle the product covered by the NOP Import Certificate. When a certifying agent issues a NOP Import Certificate, it is validating that the product is truly organic; therefore, it must have adequate control systems to verify these claims.

To address the problem of generating NOP Import Certificates for multiple shipments in short timeframes (e.g., multiple shipments of fresh produce across the border), AMS is granting the certifying agent the authority to determine whether it will issue an NOP Import Certificate for a specific shipment, or for a specific timeframe (e.g.,

weekly, monthly, season) and amount or volume ceiling. The certifying agent is responsible for ensuring that the issued NOP Import Certificate is only associated with an amount of product that has been verified to be certified organic.

(Comment) AMS received several comments that recommended a staggered implementation timeline for the NOP Import Certificate requirement to ensure certifying agents have the administrative capacity to process additional NOP Import Certificates. Several comments also expressed concern about the increased cost associated with issuing NOP Import Certificates. Comments noted that certifying agents would need to hire and train additional technical staff to comply with the proposed requirements for NOP Import Certificates.

(Response) Under the current USDA organic regulations, certifying agents are not allowed to provide certification services that are outside its administrative capacity. While a reasonable implementation period is being provided to fully update the Organic Integrity Database to generate NOP Import Certificates, certifying agents are not to issue any NOP Import Certificates without having adequate expertise and staffing to verify the organic status of products it oversees under the organic program.

(Comment) Commenters asked how certifying agents will verify whether a shipment is compliant with the USDA organic regulations based on an NOP Import Certificate.

(Response) Certifying agents that are overseeing exports of organic products to the United States must have and implement a documented organic control system for intaking and then approving or rejecting an NOP Import Certificate request. The certifying agent is responsible for ensuring that the issued NOP Import Certificate is only associated with an amount of product that has been verified to be certified organic. Certifying agents that are overseeing importers of organic products into the United States must have a system for ensuring that operations receiving organic product are receiving and maintaining NOP Import Certificates, ensuring that importers have met the

requirements of this section, and that they are not accepting more product from any providers than is authorized by NOP Import Certificates.

General applicability

(Comment) AMS received comments asking if NOP Import Certificates would be required for small, retail, and mixed shipments of organic product imported into the United States.

(Response) NOP import Certificates will be required for any commodity imported into the United States that is being manifested, sold, marketed, or labeled organic. NOP Import Certificates are required for organic commodities regardless of value or size and is not applicable for any *de minimis* exemptions under current CBP regulations. A very limited number of exemptions will be allowed for items such as, but not limited to, food donations, non-retail samples, and humanitarian efforts.

(Comment) Commenters asked if NOP Form 2110-1, NOP Import Certificate, is mandatory and whether a paper copy would be permitted. Commenters also asked if certifying agents would issue physical or digital copies of NOP-2110-1 to operations.

(Response) Only the NOP Import Certificate and its associated data, generated from the Organic Integrity Database, is a valid NOP Import Certificate. Either a paper-based or electronic NOP Import Certificate may be used. Certifying agents will determine the format it will use to provide the exporter with the NOP Import Certificate data.

ACE data entry

(Comment) We received comments requesting AMS clarify the definition of “equivalent data source” by providing additional text in § 205.273(e). Commenters requested the requirement explicitly state that USDA is the sole authority that determines equivalent data sources.

(Response) In the final rule, we have removed the term “equivalent data source.” All NOP Import Certificates will be generated using the Organic Integrity Database. AMS

provides multiple ways to upload or enter data into the Organic Integrity Database. We have determined it will be the only data source for NOP Import Certificates because it is a preexisting, proven tool that meets U.S. government security requirements, and a centralized system is needed to facilitate supply chain traceability and to assess authorized import certificate data against actual import data generated by CBP and reported back to AMS. The Organic Integrity Database allows data submittals in multiple formats, such as direct data entry, data spreadsheet uploads, and automated programming interfaces. A data dictionary is also public, allowing external parties to easily map their own systems and data exports to the tool. The Organic Integrity Database is already used and understood by certifying agents, including many accredited by both the USDA and trade partner countries. It is a system that any government can engage with that minimizes onboarding time and learning curve. Using the Organic Integrity Database as a single source of certification and import data, while allowing multiple data upload methods, will provide secure access to import data that facilitates the use of NOP Import Certificates.

(Comment) We received a number of comments about the respective roles of the exporter and importer with respect to the NOP Import Certificate. Several comments stated that the organic exporter does not have access to the CBP ACE system and is not the party that would enter the required data into ACE. Commenters recommended that the importer of record be the entity responsible for entering data into ACE. Comments stated that the proposed definition of *organic importer of record* is unclear and does not reliably identify the party capable of ensuring each shipment is associated with an NOP Import Certificate.

(Response) NOP Import Certificates must be generated by the certified organic exporter's certifying agent, using the USDA's Organic Integrity Database. Only the Organic Integrity Database can be used to generate valid NOP Import Certificates, and

only accredited organic certifying agents (USDA or under an organic trade arrangement or agreement) are authorized to use the Organic Integrity Database.

Once the NOP Import Certificate is generated in the Organic Integrity Database, the exporter's certifying agent provides the NOP Import Certificate, or data set with the NOP Import Certificate number, back to the certified organic exporter who requested the NOP Import Certificate. The certified organic exporter then provides the NOP Import Certificate to the U.S. importer or buyer, who provides it to the specific entity responsible for entering import information into the ACE system. This is typically an importer or designated Customs broker. That importer or Customs broker enters the NOP Import Certificate data into the ACE system as part of its standard import filing processes, including the Entry Summary Process. Organic certifying agents will not have access to ACE; this activity is done by the importer or its Customs broker, using the NOP Import Certificate data provided by the certifying agent to the exporter.

(Comment) Commenters asked how imported organic product would be identified in ACE without an organic Harmonized Tariff Schedule (HTS) code.

(Response) The NOP Import Certificate in ACE has been programmed to enable NOP Import Certificate entry for a wide range of products, including agricultural products and textiles, not just those with an organic HTS code. An organic HTS code is not required to upload NOP Import Certificate data into ACE.

Trade arrangements and agreements

(Comment) AMS received comments requesting that foreign-based certifying agents operating under recognition arrangements be required to list organic operations in the Organic Integrity Database. As noted by commenters, the absence of that data makes it difficult for organizations to verify the certification status of foreign-certified operations.

(Response) AMS is changing access to the Organic Integrity Database to include organic certifying agents and operations operating under organic trade arrangements or

agreements, such as equivalency and recognition arrangements. Certified organic operations covered under trade arrangements or agreements will need to be listed in the Organic Integrity Database by their certifying agents for the certifying agents to be able to generate NOP Import Certificate for valid products entering the United States as organic.

(Comment) We received comments asking how NOP Import Certificates would apply to trade of organic products under, and outside of, an equivalency arrangement.

Additionally, commenters requested more information about how NOP Import Certificates would apply to NOP-certified products traded between foreign countries.

(Response) The NOP Organic Import Certificate is required for any product imported into the United States that is being manifested, sold, marketed, or labeled organic, regardless of the product's country of origin or if that country has an equivalency determination with USDA. Organic products imported from any country with which AMS has an equivalency determination must follow the same NOP Import Certificate requirements outlined in this rule. Other countries may also have their own unique filing requirements for organic products coming into their countries; organic businesses need to consult with their supply chains to determine those requirements.

C. Labeling of Nonretail Containers.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.307	Labeling of nonretail containers. Paragraphs (a) through (c).

Accurate labeling of non-retail containers used to ship or store organic products is critical to organic integrity. Proper labeling reduces misidentification and mishandling, facilitates traceability and product verification, reduces the potential for organic fraud,

and allows accurate identification of organic product by customs officials and transportation agents.

Therefore, this rulemaking requires that all nonretail container labels must identify contents as organic and include information linking the container to audit trail documentation. Additionally, audit trail documentation associated with a nonretail container must identify the last certified operation that handled the product. Affected entities may include but are not limited to: certified and noncertified operations that store and transport organic product in nonretail containers; certifying agents; and inspectors.

Background

The organic regulations previously only required a production lot number on nonretail containers labels used to ship or store organic product. Other information—such as identification of the product as organic, and special handling instructions—were optional, but not required on nonretail container labels. Based on the NOP’s experience enforcing the organic regulations, this lack of information created gaps in the organic chain of custody, complicated the verification of organic integrity, and increased the likelihood of organic fraud.

To reduce the prevalence of organic fraud and increase oversight of organic supply chains, nonretail containers are now required to be marked with a statement identifying the product as organic and must include unique information that will link the nonretail containers to audit trail documentation. Unique identifying information could include lot numbers, shipping information, or a unique identifier for that shipment. Accurate labeling will identify contents as organic as a container moves through the supply chain; this will reduce mishandling and help maintain an audit trail and improve traceability.

Nonretail containers: description and use

Nonretail containers are defined under § 205.2 of the USDA organic regulations as “any container used for shipping or storage of an agricultural product that is not used in

the retail display or sale of the product.” Nonretail containers are used to ship or store either packaged or unpackaged organic products, and may include the following:

- Produce boxes, totes, bulk containers, bulk bags, flexible bulk containers, harvest crates and bins;
- Boxes, crates, cartons, and master cases of wholesale packaged products; and
- Trailers, tanks, railcars, shipping containers, vessels, cargo holds, freighters, barges, grain elevators, silos, grain bins, or other methods of bulk transport or storage.

Nonretail containers are not used to display organic products for sale to the consumer at retail establishments. Packages that display organic products for retail sale to the consumer must be labeled according to §§ 205.303 and 205.306.

What must be included on nonretail container labels?

Nonretail containers used to ship or store organic products must be clearly labeled with a statement that identifies the product as organic. Clearly visible organic identification alerts handlers that the contents of the nonretail container may require special care, thus reducing accidental mishandling of the product, such as treatment with a prohibited substance or commingling with conventional product during transport and storage. Operations may use abbreviations or acronyms to identify products as organic, provided that they are clear and easily understood. This provides flexibility for operations to meet the requirements of § 205.307(a)(1) and makes it easier to label containers with limited space or containers that are difficult to label due to their size, shape, material, or use.

Nonretail containers must also be clearly labeled with information that links the container to audit trail documentation (see § 205.2 for definition of *audit trail*). This could be a production lot number, shipping identification, or other unique information that handlers can use to trace the container to its associated audit trail documentation.

This creates a clear link between container and audit trail and minimizes the size of labels by allowing some information to be listed in associated documentation, instead of directly on the nonretail container label.

Operations may use temporary labels or signage to meet the requirements of § 205.307(a). This provides additional flexibility for containers that may be difficult to label due to size, shape, material, or use.

Revisions to § 205.307 do not limit the information that can be on a nonretail label. This gives operations the flexibility to include details they deem critical to the integrity of specific products. For example, an operation may opt to include special handling instructions, the USDA organic seal for qualifying products, the operation or certifying agent name, or contact information on the nonretail label.

Nonretail containers and audit trail documentation

Nonretail containers used to ship or store organic products must be labeled with information that links the container to audit trail documentation (§ 205.307(a)(2)). Such documentation must be sufficient to determine the source, transfer of ownership, and transportation of the product (see definition of *audit trail* in § 205.2) and must identify the last certified operation that handled the product (§ 205.307(b)).

Listing the last certified organic operation provides a point of contact to verify the organic status of a product and supports operations' traceability, recordkeeping, and fraud prevention requirements (§§ 205.103(b)(2)–(3) and 205.201(a)(3)). It also supports on-site inspections and supply chain traceability audits conducted by certifying agents (§§ 205.403(d)(5) and 205.501(a)(21)) by ensuring good recordkeeping of the critical transfers between certified operations.

Exception to organic identification on nonretail containers

Nonretail containers used to ship or store agricultural products packaged for retail sale with organic identification visible on the retail label are not required to identify

product as organic per § 205.307(a)(1). Examples include master cases and pallets where the organic identification (e.g., the USDA organic seal) of individual retail units is visible. These are exempt from § 205.307(a)(1) because the organic identification is visible on the retail label.

These types of nonretail containers are only excepted from the requirements of § 205.307(a)(1). All nonretail containers must be linked or traceable to audit trail documentation per § 205.307(a)(2); this ensures traceability of the product in the containers and supports organic integrity during transport, storage, and handling.

Summary of changes to the final rule

AMS made several changes to the regulatory text of the SOE proposed rule when writing this final rule. Changes to the proposed rule are discussed below and are followed by specific themes from public comment.

- AMS simplified the requirement to list full organic identification (e.g., “100 percent organic,” or “made with organic...”) to “identification of product as organic,” which provides more flexibility to operations and shortens the organic identification statement without changing the statement’s intent or its utility as immediate and clear identification of nonretail containers. This change was made in response to public comment.
- AMS revised the requirement to list production lot numbers or shipping identification. This information is now used to link a container to audit trail documentation. To reduce administrative burden and cost to operations, AMS is only requiring the most critical information on nonretail container labels: organic identification and information that links the container to audit trail documentation. This maintains traceability and integrity by requiring nonretail containers to be linked to audit trail documentation, which must identify the last certified

operation that handled the product and must be sufficient to determine the source, transfer of ownership, and transportation of the product.

- AMS removed the requirement to identify the product's certifying agent on nonretail labels because this information may be included in audit trail documentation linked to nonretail containers. Removing this requirement limits information on nonretail labels to the most critical information, thereby reducing cost and burden without sacrificing integrity.
- AMS added a requirement that audit trail documentation associated with a nonretail container must identify the last certified operation that handled the product. This allows operations to verify the source of organic products they receive and provides a record trail that certifying agents can use to conduct full supply chain traceability audits and verify organic status.
- The final rule no longer requires organic identification on nonretail containers of retail-labeled products. This avoids undue administrative burden, cost, and redundant information when organic identification is already visible on the products' retail labels.
- AMS removed the list of optional information that may be listed on nonretail container labels. This list is not necessary because operations may optionally include any additional information on nonretail labels if they wish.

Summary of public comment

Public comments strongly supported mandatory organic identification on nonretail container labels. However, many comments requested the flexibility to use alternatives like abbreviations and common names. Commenters stated that the proposed rule's requirement to use specific (and sometimes lengthy) statements would add cost and be difficult to apply to containers with limited space. Commenters also requested that AMS

require generic product names—e.g., “organic tomatoes”—on labels, claiming that this information is needed to quickly identify the contents of nonretail containers.

Other commenters requested AMS mandate additional information on large nonretail container labels to include country of origin, special handling instructions, and the USDA organic seal. Additionally, comments pointed out that nonretail labels should not be limited to the information explicitly listed in § 205.307, and requested that NOP allow operations to include other types of information on labels.

Responses to Public Comment

(Comment) We received comments requesting AMS require all nonretail containers display the information described in § 205.307, regardless of size or type (i.e., not allow exceptions for large nonretail containers used for transport or storage). Additionally, commenters noted that there was no definition or description outlining what type of containers would be exempt from the labeling requirements.

(Response) All nonretail containers of organic products must be labeled with information that links the container to audit trail documentation, regardless of size, shape, or use. This ensures information needed to verify and trace the product is available to those handling the product. Only nonretail containers used to ship or store agricultural products packaged for retail sale with organic identification visible on the retail label are excepted from the requirements of § 205.307(a)(1).

(Comment) Commenters requested the name and contact information of the certified operation be a mandatory field on all nonretail container labels because a certifying agent name alone is not sufficient to match a physical product to an organic certificate. Other commenters also requested that the operation’s address or the NOP operation ID also be included.

(Response) AMS is only requiring the most critical information on nonretail container labels: organic identification and information that links the container to audit trail

documentation. This reduces administrative burden and cost to operations. Traceability and integrity are maintained by requiring nonretail containers be linked to audit trail documentation, which must identify the last certified operation that handled the product. Audit trail documentation must be sufficient to determine the source, transfer of ownership, and transportation of the product (see *audit trail* in § 205.2).

(Comment) We received comments requesting that listing the certifying agent be optional because it was redundant for master cases of retail-packaged product and added to the cost of the label.

(Response) AMS does not require listing the certifying agent on nonretail container labels. Such information may be listed in audit trail documentation; operations may choose to do this to verify organic status of the product or determine the source, transfer of ownership, and transportation of the product. Section 205.307(c) excepts nonretail containers of retail-packaged products from listing organic identification if the retail packages clearly identify the product as organic.

(Comment) AMS received comments noting both disagreement and confusion regarding which operation/certifying agent pair is required to be on the nonretail label.

Commenters stated that the proposed revision (“producer of the product, or... the last handler that processed the product”) may not indicate the appropriate operation for verification purposes or in private labeling scenarios.

(Response) Section 205.307(b) requires that a nonretail container’s audit trail documentation identify the last certified operation that handled the product. The certifying agent that certified this handler may be listed in audit trail documentation; operations may choose to do this to verify organic status of the product or determine the source, transfer of ownership, and transportation of the product.

(Comment) We received comments stating that special handling instructions are critical to the integrity of organic products in the supply chain and requested that AMS make this

information mandatory on all labels. Commenters also inquired about what special handling instructions should include.

(Response) We are not requiring special handling instructions on nonretail container labels; this reduces administrative burden and cost to operations without risking integrity. Operations may include special handling instructions (or other information) on nonretail containers if they deem it necessary.

(Comment) AMS received comments requesting the mandatory use of tamper-evident seals on nonretail containers. Commenters argue that tamper-evident seals may help prevent fraud and mishandling of organic product.

(Response) AMS is not requiring tamper-evident seals on nonretail containers; this avoids potential undue administrative burden and costs to operations. Operations may use tamper-evident seals on nonretail containers if they deem it necessary.

D. On-Site Inspections.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.2	Terms defined. Definition for <i>Unannounced inspection</i> .
205.403	On-site inspections. Paragraphs (b)(1) and (2) and (d)(4) and (5).

On-site inspections of certified organic operations are a critically important tool used to verify an operation's compliance with the Act and the organic regulations. This rulemaking strengthens the utility of on-site inspections by requiring that certifying agents:

- Conduct a minimum number of unannounced inspections each year
- Conduct mass-balance audits during on-site inspections

- Verify traceability of product and ingredients within an operation during on-site inspections
- Verify traceability of product in an operation's supply chain back to the last certified operation during on-site inspections

These requirements will strengthen organic integrity and supply chain traceability by requiring the use of proven best practices during inspection of organic production and handling. Entities affected by this policy may include certifying agents, certified operations, and operations applying for certification. Organic stakeholders should carefully examine the regulatory text and policy discussion below.

Unannounced inspections—background

Unannounced inspections are an effective and useful tool to ensure compliance across certified operations and bolster consumer trust in the organic label. NOP previously issued an instruction (NOP Instruction 2609) on unannounced inspections, which recommends that certifying agents conduct unannounced inspections of five percent of their total certified operations per year as a tool for ensuring compliance with the regulations.²⁴ This NOP instruction was supported by a recommendation made by the NOSB in December 2011.²⁵ The organic regulations previously allowed for, but did not require, unannounced inspections, leaving this to the discretion of the certifying agent. Therefore, AMS has codified the requirement for certifying agents to conduct a minimum number of unannounced inspections annually of certified operations.

²⁴ NOP 2609, Instruction, Unannounced Inspections. September 12, 2012. Available in the NOP Program Handbook: <https://www.ams.usda.gov/sites/default/files/media/2609.pdf>

²⁵ NOSB Recommendation, Unannounced Inspections. December 2, 2011. Available on the AMS website: <https://www.ams.usda.gov/sites/default/files/media/NOP%20CACC%20Final%20Rec%20on%20Unannounced%20Inspections.pdf>

Use of unannounced inspections

To clarify the difference between unannounced inspections and full annual inspections, AMS is defining the term *unannounced inspection* as “The act of examining and evaluating all or a portion of the production or handling activities of a certified operation without advance notice to determine compliance with the Act and the regulations in this part.”²⁶ Note that unannounced inspections are different from a full annual inspection because the scope of the inspection may be limited to a portion of the operation or the operation’s activities, and certifying agents must conduct the inspection without advance notice.

Scope of unannounced inspections

Relative to a full annual on-site inspection, an unannounced inspection may be limited in scope, depth, and breadth and may cover only a portion of the operation or the operation’s activities, such as parcels, facilities, products, or a review of records. This allows unannounced inspections to be used as a risk-based tool to address specific needs, such as investigation of a complaint or high-risk area. Inspectors may conduct sampling during an unannounced inspection. Samples collected may count towards the number of samples a certifying agent must collect annually per § 205.670(d) of the organic regulations. Sample collection alone, however, does not qualify as an unannounced inspection.

When unannounced inspections are limited in scope, they are not required to follow the requirements of § 205.403(c)(2), (d), or (e). This means unannounced inspections:

- May be conducted when an authorized representative of the operation is *not* present and the inspector is not trespassing

²⁶ Compare to the definition of inspection at 7 CFR 205.2: The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

- May be conducted at any time of year
- Do not have to verify all areas or activities of the operation like a full, annual inspection
- Do not have to include an exit interview with an authorized representative of the operation

An unannounced inspection may fulfill the requirement for a full annual on-site inspection, provided that the inspector meets all requirements for an annual on-site inspection per § 205.403. This includes meeting the timing, scope, exit interview and documentation requirements for annual inspections. The exception is that the inspection would not be scheduled in advance with the operation's awareness. If an unannounced inspection will serve as the annual inspection, an authorized representative must be present.

Selecting operations for unannounced inspections

To maximize the effectiveness of unannounced inspections, certifying agents are encouraged to select operations from a range of different production and handling types, products, and locations. Operations may be selected randomly, by risk, in response to a complaint or investigation, or other criteria. The number of unannounced inspections to be conducted annually should be calculated by rounding up to the nearest whole number, so that certifying agents with very few certified operations (e.g., under 20 operations) are still required to conduct at least one unannounced inspection per year.

Planning and scheduling unannounced inspections

Unannounced inspections should be conducted without advance notice to the operation. However, some unannounced inspections may require advance notice (e.g., to ensure that portions of an operation are accessible or safe to access). Therefore, a certifying agent may notify an operation up to four hours prior to the inspector arriving onsite. As a best practice, certifying agents are encouraged to disclose their process for

unannounced inspections, including a policy on inspector access to certified operations, and to train inspectors to prevent trespassing or breaking laws when accessing an operation. An operation's refusal to allow an inspector access to any portion of the operation is a violation of § 205.403 and warrants a notification of noncompliance.

Following an unannounced inspection, an inspection report must be written by the inspector and reviewed by the certifying agent. The results of the inspection must be communicated to the inspected operation per § 205.403(f) and the certifying agent's internal protocols.

Certifying agent ability to conduct unannounced inspections

Certifying agents must be able to conduct unannounced inspections of any operation they certify. Therefore, AMS requires that certifying agents only accept applications for certification or continue certification from operations for which the certifying agent is able to conduct unannounced inspections. To ensure consistency, transparency, and accountability, certifying agents are expected to describe the areas where they operate in the written materials they provide to both applicants and certified operations, and review the locations of all operations during their application review or annual review.

A certifying agent that cannot conduct unannounced inspections in an applicant's or certified operation's location due to logistical challenges, staffing, security, or other reasons, is considered to not have the administrative capacity for certification activities in that area, consistent with § 205.501(a)(19). In this case, the certifying agent must document the specific reasons it does not have the administrative capacity to certify in that area, and must inform the applicant or certified operation to seek certification from another certifying agent. If new certification is not obtained, the operation's certification would be suspended/revoked. This process is similar to the current procedures used when a certifying agent surrenders its accreditation or is suspended/revoked.

For additional information about unannounced inspections, certifying agents may refer to NOP Instruction 2609.

Mass-balance and traceability audits during on-site inspections

Traceability of organic products is critical to verification of organic integrity. Therefore, AMS requires that certifying agents verify quantities and traceability of organic products produced or handled by an operation through mass-balance and traceability audits. Audit tools are the premier methods to verify organic integrity. The importance of audits has increased because transaction certificates, which certifying agents relied upon in the past to verify the organic status of specific loads or sales of organic products, are neither required by the USDA organic regulations nor universally issued by certifying agents.

Mass-balance audits

During on-site inspections, certifying agents must verify that the quantities of organic product and ingredients produced or purchased by an operation accounts for organic products and ingredients used, stored, sold, or transported by the operation (§ 205.403(d)(4)). Commonly known as a “mass-balance” or “in-out” audit, this verification is an effective method of detecting and discouraging organic fraud.

Mass-balances may be performed on products that are produced on an operation, but then used or stored on-site and not sold (e.g., silage produced on-site as feed for dairy animals). Mass-balance covers quantities of agricultural products; other quantitative assessments such as dry matter intake and stocking rate verification are not mass-balances. To conduct these mass-balance audits, certifying agents may choose a sub-set of products based on risk or other factors. With respect to multi-ingredient products, certifying agents may choose a single ingredient or multiple ingredients to mass-balance. When a single ingredient is selected, a best practice is to choose an ingredient that is high-risk or used in several products.

Mass-balances do not replace the recommended best practice of also conducting yield analyses at producer operations. Yield analysis looks at whether harvested quantities are consistent with expected yields. This is an important tool to assess the potential for commingling of noncertified/nonorganic products with organic products.

Traceability audits

Successful traceability within organic supply chains requires three basic elements: (1) traceability within a single operation; (2) traceability one step back from an operation in a supply chain; and (3) traceability by a third party along an entire supply chain, source to consumer.

Therefore, during all annual inspections certifying agents must verify the traceability of organic product both within an operation and verify traceability back to an operation's suppliers (§ 205.403(d)(5)).²⁷ This means that a certifying agent must verify that an operation can trace the products it produces or handles during the full time the operation possesses those products, from time of purchase or acquisition, through production, to sale or transport. This includes ingredients or products that the operation handles but may not own.

Additionally, certifying agents must verify the traceability of products from an operation's suppliers (§ 205.403(d)(5)). Because supply chains sometimes include operations that are not certified, certifying agents must verify compliance of organic products back to the last USDA-certified organic operation. Certifying agents may verify compliance back to the last certified operation by inspecting and verifying audit trail documentation and other records kept by the certified operation being inspected. This

²⁷ The third traceability element, traceability along an entire supply chain, is addressed in 7 CFR 205.501(a)(21), and discussed in this rulemaking in Section P, Supply Chain Traceability and Organic Fraud Prevention.

will ensure oversight of the critical linkages between certified operations and support full traceability and verification of organic products across supply chains.

Certifying agents must also conduct supply traceability chain audits when circumstances meet criteria defined by the certifying agent (§§ 205.501(a)(21) and 205.504(b)(7)). These audits would not be performed at every annual inspection.

Responses to public comment

Virtual/remote Inspections

(Comment) Several public comments noted that during the COVID-19 pandemic, virtual inspections, or sometimes a hybrid of virtual and on-site inspection, were temporarily used by certifying agents. Several comments asked if AMS intends to allow the use of virtual inspections for operations that have a demonstrated history of compliance or are at low risk of organic fraud.

(Response) Virtual and/or remote inspections were not included in the SOE proposed rule and AMS is therefore not setting specific policy related to virtual or remote inspections. The final regulations provide flexibility so that AMS may consider virtual inspection policy options in the future.

Unannounced inspections

(Comment) Several comments asked AMS to increase the minimum number of operations that must receive unannounced inspections beyond the five percent AMS proposed.

(Response) AMS is finalizing the proposed requirement that certifying agents must conduct unannounced inspections of at least five percent of the operations they certify. This is consistent with a 2011 NOSB recommendation and a current NOP Instruction document. AMS chose this percentage because the majority of USDA-accredited

certifying agents currently complete unannounced inspections at this frequency.²⁸

Because most certifying agents are already completing unannounced inspections at this level, this percent should be tenable for certifying agents, regardless of size. To justify a higher percentage, AMS would require additional information, industry feedback, and data to assess the potential impact. Comments did not provide justification or data to support a higher inspection percentage. However, certifying agents may choose to conduct a higher percentage of unannounced inspections to supplement their oversight and enforcement of certified operations.

(Comment) Some public comments asked if AMS intends to publish criteria for initiating or using unannounced inspections.

(Response) AMS is not adding criteria for using or initiating unannounced inspections to the regulations. Unannounced inspections may be triggered and selected by a variety of factors, including at random and in response to complaints or investigations. The regulations provide certifying agents flexibility to use unannounced inspections when and where they are most effective.

Mass-balances

(Comment) Several public comments asked if AMS is requiring one mass-balance per certification scope (i.e., crops, livestock, handling, wild crops) of an operation.

(Response) The regulatory text provides certifying agents the flexibility to determine where such audits are most needed within a single inspection.

(Comment) Some comments asked AMS if mass-balances should be performed for single-ingredient or multi-ingredient products, and if mass-balances for multi-ingredient products must balance all ingredients in the product.

²⁸ 42 of the 49 USDA-accredited certifying agents the NOP audited in calendar years 2018 and 2019 completed unannounced inspections for 5% of the operations they certify.

(Response) The final regulatory text provides certifying agents flexibility to perform mass-balance audits of both single- and multi-ingredient products. For multi-ingredient products, the certifying agent may choose to mass-balance one or more of the ingredients.

E. Certificates of Organic Operation.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.2	Terms defined. Definition for <i>Organic Integrity Database</i> .
205.404	Granting certification. Paragraphs (b) and (c).

Certificates of organic operation are an important tool used by organic stakeholders to communicate information about certified operations. Certifying agents must generate certificates of organic operation electronically using the Organic Integrity Database. Standardized, electronic certificates maintained in a publicly accessible database will help to deter and prevent the use of fraudulent certificates of organic operation. This requirement also ensures that certificates of organic operation have consistent information and format, allowing certifying agents and buyers of organic products to readily validate certificates of organic operation. Certifying agents may add their unique addenda to certificates of organic operation to provide additional details about the certified operation.

Affected entities may include certifying agents, applicants for USDA accreditation, certified operations and entities seeking to validate the certification status of an organic operation. Readers should carefully examine the regulatory text and discussion below to determine if they are affected by this action.

Background

AMS accredits nearly 80 certifying agents; only a few currently create certificates of organic operation using the Organic Integrity Database. As a result, more than 70 distinct

formats of certificates of organic operation exist in the market. This variation increases the likelihood of alteration and organic fraud. In addition, AMS consistently cites noncompliances for certifying agents who do not include all of the required information on their certificates of organic operation. Of the 49 USDA-accredited certifying agents audited by the NOP in calendar years 2018 and 2019, 16 were cited for issuing certificates of organic operation not consistent with USDA organic regulations and instruction. The use of a uniform certificate of organic operation generated through the Organic Integrity Database eliminates these inconsistencies and helps avoid noncompliances.

The requirement for uniform certificates of organic operation supports OFPA's purpose to facilitate interstate commerce of organic foods (7 U.S.C. 6501(3)). This rulemaking also addresses a 2005 NOSB recommendation to standardize information on certificates of organic operation and require certifying agents to issue and maintain certificates of organic operation from a common database.²⁹

Organic Integrity Database and certificates of organic operation

The certificate of organic operation communicates information about the organic certification of an operation. This rulemaking requires certifying agents to provide uniform certificates of organic operation that are electronically generated from the Organic Integrity Database.

AMS defines the term *Organic Integrity Database* in § 205.2 as the National Organic Program's electronic, web-based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or its successors. The Organic Integrity Database may also be referred to as the OID or INTEGRITY.

²⁹ NOSB Recommendation: Information on Certificates of Organic Operation:
<https://www.ams.usda.gov/sites/default/files/media/NOSB%20Rec%20Standardize%20Organic%20Certifications%20Certificates.pdf>

AMS is responsible for the functionality of the Organic Integrity Database and ensuring consistent content and styles of all certificates of organic operation. The general public can view information in the Organic Integrity Database online at:

<https://organic.ams.usda.gov/integrity/>

Generating certificates of organic operation in the Organic Integrity Database

Section 205.404(b) requires certifying agents to generate certificates of organic operation in the Organic Integrity Database, making it easier for the certificates to be accessed online by relevant stakeholders in the organic supply chain (e.g., other certifying agents, inspectors). Section 205.501(a)(15) requires certifying agents to maintain current and accurate data on operations they certify in the Organic Integrity Database. Together, sections 205.404(b) and 205.501(a)(15) require certifying agents to input and maintain accurate data on the operations they certify, and to generate certificates of organic operation using the Organic Integrity Database. This applies to all USDA-accredited certifying agents whether foreign- or domestic-based.

Certificates of organic operation generated in the Organic Integrity Database include the required information that stakeholders need to verify organic status of an operation. Users can also access the database to see if an operation's organic certification has been suspended, revoked, or surrendered. In addition to strengthening organic integrity, standardized certificate format and data fields facilitate and simplify verification of products, ingredients, and suppliers. The Operation Profile feature in the Organic Integrity Database also lists the generic products and services offered by an operation. The accessibility and security of this data will reduce administrative burden on certified operations that purchase organic products and ingredients, as well as certifying agents and inspectors who monitor compliance.

Certifying agents can continue using the data submission template and the web-based form to upload the required data fields into the Organic Integrity Database. Additionally,

certifying agents can transfer data from in-house databases to the Organic Integrity Database using an Application Programming Interface (API) to reduce duplicative data entry. AMS provides a data submission API guide for certifying agents on the Organic Integrity Database's User Resources page.

Addenda to certificates of organic operation

Some certifying agents use certificate addenda to supplement the information on certificates of organic operation with more details about an operation and the products it is certified to produce and/or handle. Certificate addenda may be generated and maintained in the Organic Integrity Database or by certifying agents' databases. The rulemaking allows certifying agents to continue providing their own certification addenda to communicate additional information about an operation's certification in a different format than certificates generated by the Organic Integrity Database. For example, an addendum may include information about an operation's certification to various international organic standards or the brand names of products that the operation produces and/or handles that are not included on the certificate of organic operation. Certificate addenda may be issued only for a certified operation at an approved location(s).

Section 205.404(c) requires five elements to be on any organic certificate addenda issued by certifying agents to deter organic fraud and provide consistency across certifying agents. Primarily, the addendum requirements are intended to ensure that someone viewing the document is aware that certification may be verified in the Organic Integrity Database. The accuracy of information on addenda, such as products and labeling categories, may also be verified in the Organic Integrity Database (see Operation Profiles). In summary, an addendum must identify the name, location, and contact information of the operation and certifying agent; an operation's unique operation ID from the Organic Integrity Database; addendum issue date; a link to the operation's

certificate or profile in the Organic Integrity Database; and a statement citing the Organic Integrity Database for certificate verification. Certifying agents may include other data in addition to the mandatory elements on certificate addenda.

Summary of changes to the final rule

AMS revised § 205.2 to replace the name of the proposed term “INTEGRITY” with “the Organic Integrity Database.” Additionally, AMS did not include proposed § 205.404(c)(6) which would have required expiration dates on certificate addenda. Many public comments noted that an addenda expiration date could cause confusion, as it could be mistakenly interpreted as expiration of an operation’s certification. Organic certification does not expire; it continues until surrendered, suspended, or revoked—see § 205.404(d). Further, several public comments noted that addenda expiration dates would increase workload for certifying agents, as they would need to update addenda expiration dates even if there are no other changes to a certificate of organic operation. AMS agrees with public comments and is not finalizing the requirement for addenda expiration dates. This will also encourage stakeholders to adopt the best practice of verifying certification status in the Organic Integrity Database, as this tool will include the most up-to-date operation and certification information (see § 205.201(a)(15)).

Summary of public comments

Comments generally supported requirements to including uniform information on certificates of organic operation, noting that this would reduce inconsistencies across the industry on what information is collected and maintained. Comments expressed concern about using the Organic Integrity Database to generate the certificate files and some argued that the proposed changes would instead hinder the process for certificate generation, rather than streamlining it. Some certifying agents noted that they would be more comfortable and efficient using their proprietary databases to generate certificate information and that using the Organic Integrity Database would be additional work to

enter duplicative data. Comments requested a method for certifying agents to easily upload or transfer their existing data into the Organic Integrity Database, and to generate a certificate of organic operation. In addition, comments generally opposed including an expiration date on certificates of organic operation because a certificate expiration date could be conflated with an operation's certification status.

Responses to public comment

(Comment) Comments requested that NOP change the name of the proposed term *INTEGRITY* to *Organic Integrity Database*. Commenters stated that referring to the database's nickname is not descriptive enough and could lead to confusion between the concept of organic integrity and the database.

(Response) AMS has revised § 205.2 to use the term *Organic Integrity Database* to reduce the possibility of stakeholder confusion by using the full name of the database.

(Comment) Certifying agents stated that entering operation data into their own databases and the Organic Integrity Database is duplicative work and would be a financial and administrative burden because it will require administrative staff to update both databases. Commenters also expressed concern about whether the Organic Integrity Database would have the functionality and capacity to withstand the number of people who would need to access it regularly, if the Organic Integrity Database is also used to generate certificates of organic operation.

(Response) AMS provides tools for uploading data (data submission template) and transferring data (via an API) into the Organic Integrity Database to reduce duplication. Please see the data submission API guide for certifying agents on the Organic Integrity Database's User Resources page. In addition, generating certificates pulls from the mandatory data that certifying agents must enter into the Organic Integrity Database to comply with § 205.501(a)(15). Section 205.501(a)(15) requires certifiers to enter data into the Organic Integrity Database and states certifying agents must "Maintain current

and accurate data in the Organic Integrity Database for each operation which it certifies.”

Certificate generation does not require additional data. AMS is prepared for the increased usage of the Organic Integrity Database as a result of the rulemaking and will offer outreach to certifying agents to support technology integration.

(Comment) AMS received comments requesting clarification on whether the rule requires operations to receive certificates of organic operation electronically—noting that many operations prefer (or can only receive) paper certificates.

(Response) Section 205.404(b) states that an organic certificate *may* be provided to operations electronically—however, this step occurs after a certificate has been generated electronically and does not affect how a certifying agent transmits certificates to an operation. Anyone may print a certificate from the Organic Integrity Database as needed.

F. Continuation of Certification.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.406	Continuation of certification. Paragraphs (a) and (b).

AMS has amended § 205.406 to clarify the annual update requirements for organic system plans (OSP) and to specify that certifying agents are required to conduct inspections of operations they certify at least once per calendar year. These changes maintain requirements for certified operations to provide certifying agents with updated and accurate information about their organic activities while eliminating duplicative work, and will strengthen oversight of organic operations through regular and timely inspection. Affected entities may include, but are not limited to certifying agents, certified organic operations, and operations seeking organic certification. You should carefully examine the regulatory text to determine if you or your organization may be affected by this action.

Annual updates of organic system plans

Previously, the organic regulations required certified operations to submit an updated OSP in its entirety as part of annual certification renewal. Certifying agents implemented this inconsistently: some required certified operations submit an entire OSP every year, while others required operations only to submit revisions to their OSP. To clarify OSP requirements, this rulemaking revises § 205.406(a) to allow certified organic operations to only submit sections of its OSP that have changed to its certifying agent.

Additionally, the rulemaking removes previous paragraph § 205.406(a)(3), which required that certified operations provide, along with its annual update, an update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification. This requirement was duplicative and unnecessary, as certifying agents (when issuing a notice of noncompliance) must specify a date by which a certified operation must rebut or correct noncompliances (§§ 205.662(a)(3) and 205.404(a)). Removal of this requirement reduces paperwork, simplifies the certification process, and ensures that noncompliances are resolved according to the deadline in the notice, rather than waiting until the next certification cycle.

The NOP previously described this approach in published certifying agent Instructions (NOP 2615 and NOP 2601).³⁰ This change is necessary to ensure legal enforceability, consistent practices between certifying agents, and reduce the paperwork burden of organic certification. This will not impact the requirements for certified operations to maintain an updated OSP or the requirement for an operation to notify its certifying agent of operational changes that may affect its compliance with organic

³⁰ NOP 2601 The Organic Certification Process, December 16, 2013: <https://www.ams.usda.gov/sites/default/files/media/2601.pdf>

NOP 2615 Organic System Plans, Organic System Plan Updates, and Notification of Changes, December 16, 2013: <https://www.ams.usda.gov/sites/default/files/media/2615.pdf>

regulations (§ 205.400(f)). Further, the on-site inspection of an organic operation must verify that the entire OSP is implemented as described.

Frequency and scheduling for annual inspections

Annual inspection cycles are essential to vigilant oversight of organic operations. Inconsistent interpretation of previous § 205.406 regarding inspection timing sometimes resulted in inspection frequencies longer than the annual timeframe specified in OFPA (7 U.S.C. 6506(a)(5)). For example, former § 205.406(b) was sometimes interpreted to mean that an operation may be inspected once every 18 months on an ongoing basis (i.e., two inspections over a 36-month period compared to three inspections if conducted annually). To clarify frequency of on-site inspection, this rulemaking revises § 205.406(b) to simplify the regulatory text and clearly state that inspections are to be conducted at least once per calendar year.

Revised paragraph (b) clarifies that all certified operations must be inspected at least once in a calendar year, regardless of (1) when the certified operation was last inspected and (2) when, or if, the certified operation provided its annual updates. This revision allows certifying agents flexibility to conduct on-site inspections at any time during the year (essential for verifying activities throughout the growing season, for example) to ensure that an inspection is conducted every single calendar year. Additional inspections may be needed to inspect all portions of an operation to assess full compliance of an operation (e.g., during and outside the grazing season for livestock operations). This requirement does not replace the need for additional unannounced inspections.

Summary of changes to the final rule

AMS did not make any revisions to the proposed regulatory text. The policy continues unchanged in this final rule.

Summary of public comment

Public comments largely supported changes made in the proposed rule, citing support for reduced paperwork, increased flexibility, and clear enforceability to uphold organic integrity. Some comments questioned the need for the proposed changes, citing that the work of updating an entire OSP is not significantly greater than updating portions of it.

Several comments supported revisions to section 205.406(b), which now requires certifying agents to conduct on-site inspection once per calendar year. However, commenters requested additional flexibility regarding annual inspections requirements in the face of extreme circumstances that may render an in-person inspection unsafe or unfeasible for the inspector or operation. These comments cite the COVID-19 pandemic as an example.

Other comments were generally in support of the flexibility that the revisions provide, particularly allowing inspections to occur when seasonally appropriate (and potentially reducing certifying agents' need to request additional inspections). However, a few commenters noted that the calendar year restriction may cause inspections to occur one closely after another, depending on the type of operation and harvest timeline.

Responses to public comment

(Comment) AMS received comments stating that the revisions to OSP submission requirements could lead to inconsistent information across certifying agent databases and the Organic Integrity Database.

(Response) All certifying agents are now required to maintain updated information on operations they certify in the Organic Integrity Database. This requirement will eliminate inconsistencies.

(Comment) Comments asked if certifying agents can still request full updated OSPs from operations they certify, should the certifying agent deem the proposed changes significant.

(Response) The rulemaking does not change or limit the ability of certifying agents to request information, including a full OSP, that is needed to determine an operation's compliance with the organic regulations. Paragraph 205.406(a)(4) of the regulations requires operations to provide certifying agents information that they deem necessary to determine compliance with organic regulations.

(Comment) We received comments requesting more flexibility regarding annual inspections (e.g., allowing the issuance of temporary variances, or allowing for virtual inspections) in the face of extreme circumstances that may render an in-person inspection unsafe or unfeasible for the inspector or operation.

(Response) AMS acknowledges that extreme circumstances may prevent a certifying agent from completing an on-site inspection once per calendar year. In such cases, the certifying agent may delay inspection, but the delay should be minimized and explained in the certifying agent's inspection report and records. A certifying agent's inability to consistently inspect operations annually due to access, safety, extreme weather, or other issues is a failure to carry out inspection requirements and does not fulfill the general requirements for accreditation (§ 205.501(a)(3)). When the certifying agent is unable to provide adequate oversight and enforcement, the certifying agent should not continue to certify the operation.

(Comment) AMS received comments proposing an inspection window anywhere between 7 and 17 months apart rather than 18 months, thus allowing inspectors to conduct inspections when seasonally appropriate.

(Response) The rulemaking establishes a minimum frequency for on-site inspections—at least once per calendar year—to ensure all certified operations meet OFPA's

requirement for annual inspection. If the certifying agent is unable to complete a full inspection during a time when land, facilities, and activities that demonstrate compliance can be observed (see § 205.403(c)(2)), then the certifying agent may conduct additional on-site inspections, as allowed in § 205.403(a)(3)(i), to cover unobserved portions and ensure compliance with § 205.403.

G. Paperwork Submissions to the Administrator.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.501	General requirements for accreditation. Paragraph (a)(15).

Accurate and current information about certified operations is critical for commerce and oversight in the organic sector. This rulemaking supports accessible and updated data on organic operations by requiring certifying agents to maintain current data on all operations they certify in the Organic Integrity Database. Certifying agents and certified operations may be affected by these requirements. Readers should carefully review the regulations and policy discussion to determine whether they must comply.

Background

The organic industry, including certifying agents, certified operations, consumers, AMS, and other regulatory agencies use the Organic Integrity Database to confirm the certification status of operations, organic status of products, find contact or product information for specific operations, and obtain data points for investigation and enforcement actions. Timely updates to maintain data on an operation's current status, including certified products and acreage, is necessary for efficient business transactions and informed oversight. The availability of operation data also reduces the time spent by certifying agents and by AMS responding to inquiries about specific operations because interested parties can independently access the information they need.

Mandatory reporting in Organic Integrity Database

Certifying agents are required to provide and maintain current mandatory data on operations in the Organic Integrity Database. The required data fields are listed in the INTEGRITY Data Dictionary and defined in the Glossary of Terms which can be accessed at <https://organic.ams.usda.gov/Integrity/About.aspx>. Some of the data in the Organic Integrity Database is publicly accessible. Examples of mandatory, public data fields include: certification status, scope(s) of certification (e.g., crops, livestock, handling, wild-crop), and the organic commodities produced or handled by the operation. This information is essential for certifying agents and operations to verify the organic status of operations and products and supports efficient business transactions. Organic acreage is an example of mandatory data that will not be publicly available in the Organic Integrity Database.

Update frequency

Certifying agents are to establish processes for updating data in the Organic Integrity Database in a manner that keeps information current about their certified operations. This is needed to support the industry's reliance on the Organic Integrity Database for current and accurate information about individual operations. Certifying agents are required in § 205.662(e)(3) to update the Organic Integrity Database within 72 hours of an operation's suspension, revocation or surrender of certification.

This rule removes the requirement for certifying agents to provide notices of denial of certification to the Administrator following the issuance of a notice of noncompliance to an applicant for certification (formerly § 205.405(c)). In addition, the rule removes the requirement for submission of any notices of denial of certification, notifications of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, or notification of suspension or revocation (formerly § 205.501(a)(15)(i)). Also, the rule removes the annual requirement for certifying agents to

submit, by January 2, an annual list of operations certified during the preceding year (formerly § 205.501(a)(15)(ii)). Certifying agents' adherence to noncompliance procedures in the regulations are evaluated during NOP audits, review of appeal cases and relevant complaints. The requirement for certifying agents to list operations in the Organic Integrity Database and their corresponding certification status makes the paperwork submission requirements unnecessary.

Summary of changes to the final rule

AMS renamed the term *INTEGRITY* in § 205.501(a)(15) to the *Organic Integrity Database*.

Summary of public comment

Comments were largely in support of the proposed revisions, citing that the changes remove an unnecessary and redundant step from certifying agents' day-to-day operations. Commenters also noted that codifying global use of the Organic Integrity Database and maintaining "accurate and current" data are both critical to ensuring organic integrity. Commenters noted that the regulatory text does not explain how often certifying agents should update operation data.

Responses to public comment

(Comment) Comments requested that AMS require certifying agents to upload and maintain data in the Organic Integrity Database on operations that are no longer certified, were denied certification, or withdrew certification with adverse actions on record.

(Response) The Organic Integrity Database can identify applicants for certification that were denied or withdrew from certification. AMS encourages certifying agents to enter those operations into the Organic Integrity Database, however, this is not a required reporting element. The Organic Integrity Database includes all operations which are no longer certified because they are suspended, revoked, or surrendered.

(Comment) Comments noted that the rule does not describe the data fields that certifying agents are required to complete in the Organic Integrity Database.

(Response) The Data Dictionary provides a list of all data fields for the Organic Integrity Database (<https://organic.ams.usda.gov/Integrity/About.aspx>). The Data Dictionary will be updated upon implementation of this rulemaking to make all current fields mandatory. AMS may add more mandatory fields in the future based on industry and NOP needs.

(Comment) Comments requested that certifying agents be required to update the Organic Integrity Database within 72 hours of any changes to crops, products, acreage, or certification status.

(Response) The rule does not require certifying agents to update all required data fields within a certain timeframe, as certifiers need flexibility to create their own systems for updating and maintaining current data in the Organic Integrity Database. However, AMS does require certifying agents to update certain data fields within a specified timeframe. For example, § 205.662(e)(3) requires certifying agents to update the Organic Integrity Database with changes to an operations certification status within 3 business days. The Data Quality Minimum Standards and Best Practices provides recommendations for the minimum frequency to update specific data fields in the Organic Integrity Database.³¹

H. Personnel Training and Qualifications.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.2	Terms defined. Definition for <i>Certification review</i> .
205.501	General requirements for accreditation. Paragraphs (a)(4), (5), and (6).

³¹ Available in the Organic Integrity Database: <https://organic.ams.usda.gov/integrity/About.aspx>

The USDA organic regulations require that certifying agents use a sufficient number of trained and qualified inspectors and certification review personnel with expertise in organic production and handling. This rulemaking enhances existing requirements with detail about the qualifications that organic inspectors and certification reviewers must have in order to work for certifying agents. By clarifying the necessary technical skills, qualifications, and knowledge needed to conduct organic inspections and certification review, AMS ensures that inspectors and certification reviewers are better prepared to verify organic compliance, which further strengthens organic integrity across all levels of the supply chain and upholds confidence in the organic label among consumers.

The rule adds new requirements for certifying agents, inspectors, and certification personnel:

- Certifying agents must verify that all inspectors and certification personnel they contract with or hire have the minimum required training, skills, and knowledge
- Inspectors and certification personnel must meet a minimum baseline of knowledge, skills, and experience before beginning inspection or certification review activities
- Inspectors and certification personnel must meet annual training requirements to continue inspection or certification review activities
- Certifying agents must conduct periodic observations of inspectors during inspections (“witness inspections”) as a part of their annual evaluation activities
- Certifying agents must maintain policies, procedures, and records regarding inspector and certification review personnel training and evaluation

The provisions in this chapter affect current and potential organic inspectors, certification review personnel, and certifying agents who employ or contract with inspectors or certification review personnel. Some provisions apply directly to certifying agents’ hiring and evaluation processes. Others clarify the amount of training inspectors

are required to do to maintain compliance to the organic regulations. The following discussion provides further detail on the provisions and AMS's responses to comments received on the proposed rule.

Background

To continue certification, a certified organic operation must undergo an on-site inspection at least once a year. Organic inspectors visit certified organic operations to thoroughly investigate the operation's processes, facilities, and records. Inspections vary by type and complexity of operation, but generally an inspector will review fields to investigate pest management, soil fertility management, buffer zones, and other production techniques; inspect storage and preparation areas for evidence of commingling or contamination with substances prohibited in organic; review records and invoices; conduct mass-balance, traceability, and yield analyses; and interview a representative of the operation. The inspector may also collect samples to test for pesticide residues. The inspector then prepares an inspection report that the certifying agent uses to evaluate the operation's compliance with the organic regulations. In addition to regular, once-a-year scheduled inspections, organic inspectors also conduct unannounced inspections, which are conducted without advance notice and are often used to target a more limited, but higher-risk, portion of an operation to ensure compliance (see the "On-Site Inspections" portion of this rule for more detail).

Organic inspectors and review staff are therefore the most direct form of enforcement and verification because they inspect certified organic operations onsite and report their findings to certifying agents. Persons performing certification review activities also ensure organic integrity by reviewing these inspection reports along with organic system plans, inputs, and other certification documents that are used to determine compliance with the organic regulations and grant continued certification. The role as

inspectors and reviewers has only grown more critical as organic operations and supply chains become more complex and diverse.

Inspection and certification review are complex professions that require detailed and highly specialized knowledge of organic regulation and agricultural practices and strong observation, communication, and investigation skills. Without highly qualified inspectors and certification review personnel, loss of organic integrity—either unintentional or fraudulent—would go unnoticed and the organic certification system would fail. Therefore, these personnel must adhere to consistent standards of knowledge, skill, and experience, relevant to the scope and complexity of the organic operations they inspect and review. Consistent standards will ensure effective oversight and review of organic operations, catching and preventing mishandling and fraud at critical points in the organic supply chain.

The rapidly increased complexity and scale of the organic market has multiplied opportunities for mishandling of organic products and fraud, especially as supply chains for organic products increasingly depend on imported goods. In its February 2018 recommendation, the NOSB referenced “well-publicized incidents of proven fraudulent imports in the last year” as a compelling reason to ensure the industry has “qualified inspectors experienced in a broad range of operations diverse in scope and scale.”³² For example, a May 2017 *Washington Post* investigation found that millions of pounds of imported corn, soybeans, and ginger had been fraudulently labeled organic, and inconsistent inspection practices were partly to blame.³³ Additionally, public comments from accredited certifying agents and organic inspector associations agreed that minimum

³² NOSB Formal Recommendation, Inspector Qualifications and Training, May 29, 2018: <https://www.ams.usda.gov/sites/default/files/media/CACSIInspectorQualificationsRec.pdf>

³³ Peter Whoriskey, “The labels said ‘organic.’ But these massive imports of corn and soybeans weren’t.” *Washington Post*. May 12, 2017. https://www.washingtonpost.com/business/economy/the-labels-said-organic-but-these-massive-imports-of-corn-and-soybeans-werent/2017/05/12/6d165984-2b76-11e7-a616-d7c8a68c1a66_story.html?utm_term=.97e7f3942427&itid=lk_inline_manual_7

training and qualification requirements for inspectors are necessary to detect breach of organic integrity and fraud. AMS recognizes that in a diverse market where operations can choose their own certifiers, one critical element of protecting organic integrity and preventing fraud is ensuring that all organic inspectors and reviewers are held to the same high standards of training and experience.

The regulations previously lacked specific detail about qualifications, experience, and continual training for inspectors and certification reviewers. Certifying agents currently set their own policies and minimum qualifications to hire inspectors and reviewers, creating inconsistency in on-site inspection and certification review. Further, many inspectors are independent contractors who are responsible for establishing and maintaining their own knowledge base. This diversity of background and training creates an inconsistent baseline of knowledge and skill.

In 2012, NOP issued a memo to clarify that all inspectors and reviewers, whether staff or independent contractors, must possess the expertise and qualifications needed to evaluate compliance with the USDA organic standards.³⁴ Additionally, the NOSB provided recommendations in 2018 to address the need for specific qualification and training requirements for inspectors and persons performing certification review.³⁵ This rulemaking codifies the general policy in the 2012 memo and addresses the NOSB recommendations by describing baseline qualifications for certifying agent personnel.

To clarify the portions of this policy that apply to certification review personnel, AMS defines the term *certification review* as “the act of reviewing and evaluating a certified operation or applicant for certification and determining compliance or ability to comply with the USDA organic regulations.” The term does not encompass performing

³⁴ NOP Memo: Criteria and Qualifications for Organic Inspectors; April 2012: <https://www.ams.usda.gov/sites/default/files/media/NOP-Notice-OrganicInspectorCriteria.pdf>

³⁵ NOSB Formal Recommendation, Inspector Qualifications and Training, May 29, 2018: <https://www.ams.usda.gov/sites/default/files/media/CACSIInspectorQualificationsRec.pdf>

an inspection, which is separately defined in § 205.2.³⁶ Examples of certification review includes reviewing applications for certification, reviewing certification documents, evaluating qualifications for certification, making recommendations concerning certification, or making certification decisions and implementing measures to correct any deficiencies in certification services. Establishing baseline qualifications for the personnel conducting these activities will lead to greater consistency in certification review and decision.

General requirements

Section 205.501(a)(4) requires that certifying agents “continuously use a sufficient number of qualified and adequately trained personnel” to implement and comply with the organic regulations. Certifying agents must maintain adequate staffing levels and the range of expertise needed to perform the full range of certification activities, including inspection and certification review. This includes maintaining an inspection staff to timely complete initial on-site inspections, annual inspections for all operations it certifies, unannounced inspections on a minimum of 5 percent of the operations it certifies annually (see § 205.403(b)), and any other inspections needed to ensure compliance with the regulations.

Certifying agents sometimes use contracted or volunteer personnel (i.e., persons not directly employed by the certifying agent) to inspect operations or complete certification review. Therefore, certifying agents must ensure that all inspectors and certification review personnel—including staff, contractors, and volunteers—meet the requirements of § 205.501(a)(4)–(6). This means that any person performing inspection or certification review activities must meet these requirements, regardless of their work or contractual

³⁶ § 205.2 *Inspection*. The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

relationship with the certifying agent. This ensures consistent inspection and certification review by all certifying agents.

Knowledge, skill, and expertise

Certifying agents must demonstrate that all personnel they use to conduct inspection and certification review continuously maintain knowledge and skills that qualify them to perform duties as assigned (§ 205.501(a)(4)(i)(A) and (a)(4)(ii)(A)). These paragraphs detail the minimum knowledge and skills that inspectors and certification reviewers must have. Because inspectors and certification reviewers perform different functions, each must meet different baseline criteria, although there is some overlap, such as knowledge and skill of the organic regulations, traceability audits, and mass-balance audits.

Certifying agents must demonstrate, as part of their accreditation process, that any inspectors or certification reviewers they use have sufficient knowledge in organic standards and practices to successfully understand, verify, and document an operation's compliance or noncompliance with the organic regulations.

The requirements in the rulemaking are based on NOSB recommendations, public comments, and the NOP's own experience auditing certifying agents. AMS chose these specific skills because they are essential to inspection and certification review. These requirements will ensure that inspectors and certification review personnel can accurately interpret the regulations and standards, and consistently apply critical skills when inspecting and assessing compliance. This will address the current regulation's lack of specific qualifications, experience, and continual training for inspectors and reviewers.

Certifying agents must also demonstrate the expertise of all personnel they use to conduct inspection and certification review (§ 205.501(a)(5)). Critically, this means all inspection and review personnel must have expertise in knowledge of certification to the USDA organic standards. Certifying agents must also demonstrate their personnel must have education, training, or professional experience in the fields of agriculture, science,

or organic production and handling that relates to assigned duties. This requirement to demonstrate expertise will facilitate more robust accreditation audits of certifying agents and ensure more consistent oversight of certifying agents. Together with the above knowledge and skills, this requirement to maintain adequate expertise will also promote development of a uniform, high-quality base of organic inspectors and certification reviewers.

Training

Organic inspectors and certification reviewers must complete regular training relevant to their duties. Training may include courses, webinars, training sessions, field days, seminars, conferences, shadowing other inspectors on their inspections, and directed readings on relevant topics. Certifying agents may determine if specific trainings fulfill the requirements. Relevant training courses available on the Organic Integrity Learning Center (OILC) may also meet the annual training requirements. When the minimum training hours are completed, certifying agents must still ensure that each inspector and certification reviewer has the training that is sufficient to competently perform assigned inspections or duties.

Sections 205.501(a)(4)(i)(B) and 205.501(a)(4)(ii)(B) require inspectors and certification review personnel with less than one year of experience to complete at least 50 hours of training on USDA organic standards, inspection protocols, and organic production and handling practices. This requirement will help ensure new inspectors and certification review personnel are adequately prepared for their duties. The proposed rule had included a lower number of hours across all staff, new and experienced. Commenters suggested that less-experienced staff require more hours of training than existing staff. AMS agrees with public comments and has raised the initial training requirement for less-experienced staff to 50 hours, which is a reasonable balance that

aligns with industry best practice and will ensure staff are adequately prepared to perform inspection and certification duties.

Onboarding for new inspectors or certification reviewers hired by certifying agents may count towards the 50-hour requirement, as can other qualifying training they complete in their first year performing inspection or certification review duties. Any onboarding that counts towards the training would need to be technical rather than administrative to qualify as relevant training. New inspectors must complete the 50 hours of training, at minimum, before they conduct inspections independently. This allows new inspectors to gain practical training through shadow inspections. Training requirements apply equally to inspectors who are hired as employees and contractors of certifying agents; initial training received must sufficiently address the scope and complexity of work these personnel encounter when performing their duties.

Sections 205.501(a)(4)(i)(B) and 205.501(a)(4)(ii)(B) detail training requirements for inspectors and certification reviewers with more than one year of experience. Inspectors and certification reviewers must complete relevant ongoing training appropriate to their existing skills, expertise, and scope of work. The annual minimum is 10 hours per year for personnel inspecting or reviewing one area of operation (i.e., crops, wild crops, livestock, and handling). Five additional hours of annual training are required for each additional scope or area of operation. For example, an inspector who only inspects crop operations (i.e., a single area of operation) must complete at least 10 hours of annual training; an inspector who inspects crop, livestock, and wild crop operations (i.e., three areas of operation) must complete at least 20 hours of training annually. Because there are four scopes of certification in the USDA organic regulation (crops, livestock, handling, and wild crops), the maximum number of training hours an inspector would be required to complete annually would be 25 hours (10 hours of training for the first scope of certification, plus 5 hours for each of the additional 3 scopes of certification).

AMS chose these training requirements based on review of public comment and review of established industry norms. AMS agrees with public comments that new inspectors will require more robust initial training and certifying agent personnel may require more or less annual training depending on how many areas of operation they inspect or review. Therefore, relative to the proposed rule, AMS is requiring 50 hours of training for new personnel, and 10 hours plus 5 hours per additional area of operation for more experienced inspectors.

AMS chose the 50-hour requirement for new inspectors because it aligns with industry best practice. Some certifying agents commented that the proposed 20-hour requirement for new inspectors was adequate, while others maintained that 75 – 100 hours was necessary; 50 hours is a median within that range. The 50-hour requirement also aligns closely with the Accredited Certifier’s Association’s “Guidance on Organic Inspector Qualifications,” which recommends initial inspector training that totals 43 – 46 hours plus several mentored inspections and monitored reports.³⁷ Finally, many certifying agents currently require new inspectors to complete the International Organic Inspector Association’s (IOIA) basic training, a 5-day course requiring approximately 40 hours to complete,³⁸ plus additional field observation and training that together total to 50 hours of training.

AMS chose an annual training requirement of 10 hours plus 5 hours per additional scope for more experienced inspectors because it is consistent with standards established by other agencies or organizations (e.g., Preventive Controls Qualified Individuals per 2011 Food Safety Modernization Act, ISO 9001 Global Certified Lead Auditor), and because it increases flexibility by allowing more or less total annual training hours based

³⁷ “Guidance on Organic Inspector Qualifications,” Accredited Certifiers Association, Inc., February, 2018, <https://www.accreditedcertifiers.org/wp-content/uploads/2018/02/ACA-Guidance-on-Inspector-Qualifications-with-IOIA-Evaluation-Checklist.pdf>

³⁸ IOIA Basic Training: <https://www.ioia.net/training-program-overview/>

on the areas of operations inspected or reviewed. These requirements will ensure that inspectors and reviewers receive annual training that is appropriate for the level and scope of their duties.

In certain cases, certifying agents may not be able to prescribe specific training to contracted inspectors or certification review personnel. However, certifying agents must use a sufficient number of qualified and trained personnel (§ 205.501(a)(4)) and demonstrate that all persons with inspection and certification review responsibilities have expertise in organic production and handling (§ 205.501(a)(5)). This means that certifying agents must ensure any contractor used to conduct inspection or certification review activities meets the training requirements described in the regulation.

Experience

In addition to training, § 205.501(a)(4)(i)(C) requires that certifying agents demonstrate that the inspectors they use have experience that prepares them to conduct their assigned duties. Certifying agents must demonstrate that inspectors have at least 2,000 hours of relevant experience that prepares them for the areas of operation they will be assigned (i.e., crops, livestock, handling, or wild crops). Both this baseline experience requirement and the 50-hour training requirement must be met before inspectors can independently inspect organic operations. An experienced inspector may advance to inspect more complex operations based on performance.

The proposed rule specified one year of experience. This was consistent with the 2018 NOSB recommendation and generally supported by public comments. However, because public comments noted that “one year” is unclear and can be interpreted differently, AMS has chosen a more specific 2,000-hour requirement. This is equivalent to one year of full-time work (accounting for vacation and time off) and expands the pool of qualifying experiences because the hours can be obtained across multiple years, from one or more jobs, internships, or other qualifying activities.

Eligible types of experience include but are not limited to: work on a farm or ranch; agricultural extension work; agricultural education; internships; apprenticeships; experiential education; 4-H; Future Farmers of America; other inspection or auditing work; management of an organic food handling operation; food processing research; or natural resource management work. Qualifying experience is not restricted to paid work, and may include volunteer work or education.

This minimum experience requirement is supported by § 205.501(a)(5), which requires that certifying agents demonstrate that all persons with inspection or certification review responsibilities have education, training, or professional experience that relates to the duties they will perform.

Field evaluation of inspectors

Section 205.501(a)(6) requires certifying agents to ensure that every inspector they use is evaluated while performing an inspection at least every three years. Inspectors with less than three years of organic inspection experience must be evaluated every year. The regulatory text refers to observing an inspector while they are inspecting an operation as a “witness inspection.” This term is used by the International Standards Organization to refer to observations of inspections to ensure proper adherence to inspection procedures and the standards to which the inspection is being made.

The rulemaking’s field evaluation requirements are consistent with a 2016 NOSB proposal and accepted industry guidance from the Accredited Certifiers Association.³⁹ In addition, public comments supported this evaluation frequency, including annual evaluations for inspectors with less than three years of inspection experience. The

³⁹ “Personnel Performance Evaluations of Inspectors” proposal, December 13, 2016: <https://www.ams.usda.gov/sites/default/files/media/CACSIInspectorsProposal.pdf>
The Accredited Certifiers Association, Inc. is a 501(c)(3) non-profit educational organization created to benefit the accredited organic certifying agent community and the organic industry: <https://www.accreditedcertifiers.org/>

rulemaking is therefore aligned with industry best practice, and will ensure that the performance of all inspectors is consistently monitored and evaluated by certifying agents.

The above requirement is a minimum and certifying agents have the option of conducting witness inspections more frequently than the above guidelines to verify an inspector's ability to successfully conduct inspection duties. For example, certifying agents may decide to conduct additional witness inspections if there is a sudden change in the complexity of an operation being inspected, or if inspection reports show deficiencies in an inspector's skill or knowledge.

To ease the burden on certifying agents and inspectors, certifying agents may share witness inspection reports with each other, but each certifying agent must demonstrate that they have evaluated each inspector's performance in accordance with their own internal personnel policies and procedures. Certifying agents may use employees or contractors to perform the witness inspections, provided they are qualified to perform such duties (e.g., a witness inspection for a diversified crop operation should be overseen by an evaluator with adequate experience in inspecting diversified crop operations). A key indicator of an individual's qualifications to conduct witness inspections is whether that person can perform the type of inspections they are evaluating.

To ensure that witness inspections are effective and consistent, certifying agents must maintain procedures for conducting and documenting them, and maintain records of all witness inspections of inspectors they have conducted (§ 205.501(a)(6)(ii)). These records may include a quantitative or qualitative evaluation of the inspector, along with details on where, when, by whom, and on what area of operation the inspection was conducted. This requirement will facilitate more robust accreditation audits and ensure more consistent oversight of certifying agents.

Witness inspections are intended as one tool to help certifying agents maintain, evaluate and improve inspector quality, but certifying agents are also expected to take corrective action appropriate to remedying gaps and deficiencies in knowledge and skills. For example, if a witness inspection identifies problems with an inspector's report writing, then a desk audit of additional inspection reports may be appropriate to address any shortcomings. Conversely, if an inspector misses a significant noncompliance while inspecting an operation, the certifying agent may decide to conduct a follow-up witness inspection of the inspector.

Summary of changes to the final rule

AMS made several changes to the proposed regulatory text when writing this final rule. Changes to the final rule are discussed below and are followed by responses to specific themes from public comment.

- In § 205.501(a)(4)(i) and (a)(4)(ii), AMS changed “scale” to “complexity” because public comments noted that scale does not always equate to greater complexity. AMS agrees with public comments and included “complexity” in the rulemaking to highlight its importance in determining appropriate qualifications for inspectors and reviewers.
- In § 205.501(a)(4)(i)(A) and (a)(4)(ii)(A), AMS replaced “auditing” with “traceability audits” and “mass-balance audits.” This addresses public comments that requested additional specificity about the meaning of “audit.” The new language more closely aligns with accepted and well-understood industry terminology and more clearly describes the knowledge and skills that certifying agents must ensure their inspectors and reviewers possess.
- AMS revised the proposed annual training requirement of 20 hours in § 205.501(4)(i)(B) and (4)(ii)(B). Inspectors and reviewers must complete a baseline of 10 hours of training, plus an additional 5 hours for each additional

area of operation they inspect or review. Inspectors and reviewers with less than one year of inspection experience must complete 50 hours of training within their first year. This revised requirement is consistent with established industry training standards but is also more flexible because it allows for more or less total annual training hours based on the experience of the inspector or reviewer and the areas of operations they inspect or review. This requirement will ensure that inspectors and reviewers receive annual training that is appropriate for the level and scope of their duties.

- AMS updated proposed § 205.501(a)(4)(i)(C) from “field-based experience related to both the scope and scale of operations they will inspect” to “experience relevant to the scope and complexity of operations they will inspect.” We removed “field-based” because that term was unclear and could be interpreted too narrowly. Using “scope and complexity” focuses the requirement on experience relevant to the type of inspections to be performed.
- AMS changed the one-year experience requirement in § 205.501(a)(4)(i)(C) to 2,000 hours in response to comments that requested more specificity and a clear metric for verifying compliance. A 2,000-hour requirement is clearer, will promote consistent implementation among certifying agents, will allow inspectors to combine qualifying experience from more than one activity, and was supported by public comments.
- In § 205.501(a)(6), AMS added “witness inspection” to refer to certifying agents observing inspectors as they inspect an operation. This change aligns with industry and international convention and more clearly describes the requirement.
- AMS revised § 205.501(a)(6) to clarify that certifying agents must conduct annual witness inspections of inspectors with fewer than three years of experience. This change is consistent with industry best practice and will ensure that the

performance of new inspectors is consistently monitored and evaluated by certifying agents.

Summary of public comment

Many public comments focused on the proposed number of required hours of continuing education, with a mix of comments that believed that 20 hours annually is sufficient, and others arguing that 20 hours would not be sufficient. A few comments requested flexibility in how inspectors meet the education requirements, suggesting that added flexibility would help them complete the education more easily and reduce costs for certifying agents.

Some comments expressed concern that the proposed requirement of one-year of field-based experience was restrictive, and that the proposed rule was not specific enough about what types of experience would qualify. AMS also received several comments noting that using years as a metric is not an adequate measure for experience; several comments suggested a minimum number of hours per year as an alternative.

Several comments discussed inspector evaluations, with most of these comments supporting in-person evaluations once every three years, and others recommending more frequent evaluations for new or inexperienced inspectors.

Responses to public comment

Specified additional knowledge, skills, and experience

(Comment) One comment stated that labor laws prevent certifying agents from requiring contract inspectors to undertake specific training.

(Response) The regulations do not require contract inspectors to complete training specified by certifying agents; however, certifying agents must demonstrate that all inspectors, including contract inspectors, complete training that is relevant to inspection. Certifying agents can recommend or offer courses to contract inspectors, but may not be able to require completion of specific training courses. Certifying agents should review

inspector training logs or other records to ensure that the inspector has completed the required number of hours and that the training is appropriate to inspectors' skill and role.

(Comment) Comments expressed concern that a list of skills, knowledge, and experience detailed in §205.501(a)(4)(i)(A) may limit the pool of organic inspectors, and thus limit the capacity of certifying agents to inspect operations. Comments stated that specific qualifications should be based on the scope of inspections performed by individual inspectors.

(Response) The list of qualifications specified in this section are not unique to any specific type of organic operation, but are important for all inspection and certification review activities, regardless of area of operation. All inspectors must meet the general qualifications listed in § 205.501(a)(4)(i)(A). Specific qualifications should be based on the scope of inspections performed—§ 205.501(a)(4) requires certifying agents to demonstrate that inspectors have qualifications to inspect the scope and complexity of the operations assigned.

(Comment) Comments recommended including recordkeeping, mass-balance audits, traceability/trace-back audits, DMI calculations, biosecurity, cultural training, and internal control systems for producer groups as areas where inspectors must demonstrate adequate knowledge and skills.

(Response) AMS expanded the list of qualifications in the rulemaking to include mass-balance audits and traceability audits. These additions support changes to the USDA organic regulations for supply chain traceability and on-site inspections as a result of this rulemaking. DMI calculations, biosecurity, and internal control systems for producer groups are specific to particular types of operations, and AMS is not mandating these topics for general organic inspector qualifications. Although knowledge of recordkeeping is not explicitly included, some certifying agent personnel may need this

knowledge if it pertains to their duties (e.g., personnel who conduct supply chain traceability audits).

(Comment) Comments recommended requiring special qualifications or experience for inspectors who inspect high-risk operations, including special training requirements for producer group operations.

(Response) AMS is not including special training requirements for inspectors of high-risk operations or producer group operations. Section 205.501(a)(4)(i) requires certifying agents to demonstrate that their inspectors are qualified to inspect the operations of the scope and complexity assigned. If an inspector is to inspect high-risk operations or producer groups, then they must be qualified to inspect those types of operations.

(Comment) Comments recommended clarifying that import/export skills are needed only if relevant, as not all certifying agents deal with import or export of organic products.

(Response) AMS is keeping import/export requirements in the knowledge areas required for all inspectors. Because this rule requires an NOP Import Certificate for each organic shipment imported to the United States, all inspectors must have knowledge of import and/or export requirements and how they are implemented. Inspectors who regularly inspect importing or exporting operations, or operations adjacent in the supply chain, may require more advanced import/export expertise.

Training requirements

(Comment) Some comments stated that an annual training requirement violates labor laws regarding contractors. Commenters claimed certifying agents cannot provide the training to contract inspectors, so these inspectors will need to pay for the training, which could lead to higher inspection fees.

(Response) All inspectors must meet the hourly annual requirements for training that is relevant to their inspection work. While certifying agents cannot require inspectors to

complete trainings, certifying agents must ensure all contract inspectors they use meet the training requirement. The rulemaking adds clarifying detail to existing training requirements to ensure consistent implementation by certifying agents. In addition, there are various trainings available for free, such as the online Organic Integrity Learning Center, which offers 33 courses averaging 3 – 4 hours per course. Additional no-cost resources that could qualify for training include resources published by universities, the USDA, or other organic experts (e.g., plant identification databases, university extension courses, recorded lectures, informational webpages) and organic farming conferences. Furthermore, certifying agents commonly offer no-cost activities that can count as training, such as updates to inspection procedure, overviews of changes in organic regulation, supervised inspections, or field visits. Because of the wide availability of no-cost training, and because the rule’s hourly training requirement is consistent with what the industry already practices, AMS does not believe this requirement will result in additional costs for inspectors beyond what is accounted for in the rule’s economic analysis, or affect the cost of inspection.

(Comment) Comments stated that the number of required training hours should depend on how many different types of operations are inspected by a particular inspector.

(Response) AMS revised the training hour requirements in the rulemaking based on the types of operations inspected—see § 205.501(a)(4)(i)(B) and (a)(4)(ii)(B).

(Comment) Comments showed concern that a specific numerical training requirement is not appropriate. They stated that the required content in the training is critical, not the number of training hours.

(Response) The annual training minimum is required to ensure the regulation’s specified knowledge, skills, and experience requirements are effectively implemented.

Establishing a minimum number of training hours sets a clear baseline for inspector and

certification reviewer knowledge that promotes consistent implementation of the regulation by certifying agents.

Experience requirements

(Comment) Comments opposed the requirement that inspectors have one year of field-based experience, asserting it was difficult to interpret and may limit the pool of potential inspectors.

(Response) AMS agrees that the proposed use of “field-based” experience may be interpreted narrowly (e.g., only farming and organic inspection experience) and that this may limit the pool of potential new organic inspectors. The final rule is updated to reference “relevant” rather than “field-based” experience. This change supports the use of a broader pool of qualified candidates, such as persons with auditing or food handling experience.

(Comment) Comments recommended changing the proposed requirement for one year of experience to a specific number of hours of related experience.

(Response) AMS incorporated this recommendation into the final rule. Inspectors are required to have at least 2,000 hours of relevant experience prior to conducting their first inspection. This is equivalent to one year of full-time work, and can be obtained across multiple years, from one or more jobs, internships, or other qualifying activities. This clarifies the requirement and expands the pool of qualifying experiences across an individual’s career and education.

(Comment) Comments recommended AMS adopt a “mentoring and evaluation system” for inspectors in lieu of a one-year field-based experience requirement because the proposed requirement was vague. Comments stated requiring experience based on scope and scale was seen as overly prescriptive and would limit the pool of qualified inspectors.

(Response) The rulemaking does not codify an inspector mentoring program. However, a mentorship program may be used by a certifying agent to improve the quality and

proficiency of their inspectors. Mentorships may also count towards the 2,000-hour minimum experience requirement, provided that the certifying agent can demonstrate that the mentorship provided experience relevant to inspection.

Field evaluation of inspectors/witness inspections

(Comment) Several comments recommended that witness inspections occur more frequently than once every three years, or that NOP issue guidance for how to determine when witness inspections should be more frequent.

(Response) Certifying agents may conduct witness audits more frequently than once every three years “if warranted.” However, certifying agents must also maintain documented policies, procedures, and records for annual performance evaluations and witness inspections (§ 205.501(a)(6)). This means that a certifying agent may choose to conduct witness inspections more frequently than required by the regulation (e.g., to monitor inspectors with performance issues), but that the reason for more frequent witness audits should be justified and documented in the certifying agent’s policies and procedures.

Additionally, AMS increased the frequency of witness inspections for inspectors with less than three years of experience from once per three years to annually. This change was made to ensure that the performance of new inspectors is consistently monitored and evaluated by certifying agents.

(Comment) Comments recommended allowing virtual or remote witness inspections.

(Response) Virtual and/or remote witness inspections were not included in the SOE proposed rule and AMS is therefore not setting specific policy related to virtual or remote witness inspections. The final regulations provide flexibility so that AMS may consider virtual witness inspection policy options in the future.

(Comment) Comments recommend allowing certifying agents to share inspector evaluation reports with other certifying agents following witness inspections.

(Response) AMS has addressed this recommendation in the rulemaking. Certifying agents may share witness inspections reports with each other. However, certifying agents using an inspector performance evaluation or witness inspection report from another certifying must demonstrate that they have evaluated the inspector's performance in accordance with their own internal personnel policies and procedures.

(Comment) Several comments expressed concern that the proposed language would not allow contractors of a certifying agent to perform witness inspections.

(Response) Certifying agents may use contractors to perform witness inspections. However, the contracted personnel performing the witness inspection must be qualified to evaluate the inspector (§ 205.501(a)(6)(i)).

(Comment) One comment stated that new inspectors should be shadowed on 10 inspections during their first year, in addition to the proposed 20-hour training requirement.

(Response) AMS has not included this recommendation in the rulemaking. Witness inspections will assess inspectors as they perform their duties, with more frequent witness inspections of less experienced inspectors. Comments did not demonstrate the benefit of shadowing, although certifying agents may use this method if it is documented in their policies and procedures for witness inspections.

I. Oversight of Certification Activities.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.2	Terms defined. Definition for <i>Certification activity</i> and <i>Certification office</i> .
205.501	General requirements for accreditation. Paragraph (a)(22).
205.665	Noncompliance procedure for certifying agents. Paragraph (a).

This rulemaking revises the USDA organic regulations at §§ 205.2, 205.501(a)(22) and 205.665(a) to clarify AMS's authority to oversee the activities of certifying agents. Certifying agents must notify AMS when opening any certification office that conducts certification activities. In addition, this rulemaking clarifies that AMS may issue notices of noncompliance to certifying agents based on the certification activities of a party working on behalf of a certifying agent.

Certifying agents, applicants for accreditation, and certified operations may be affected by these requirements. Readers should carefully review the regulations and policy discussion to determine if they may be affected by this action.

Background

Certifying agents commonly have multiple offices to ensure they provide adequate services to their clients. However, certifying agents sometimes open new certification offices without reporting this to AMS. Some certification offices operate independently and in different countries or regions than a certifying agent's main office. AMS cannot provide oversight (regular audits and reviews) or enforcement of offices of which it is not aware. This can lead to inconsistent application and enforcement of the regulations across certifying agents. To address these gaps in oversight, the 2018 Farm Bill amended OFPA to require certifying agents to report new certification offices to AMS within 90 days of opening.⁴⁰

AMS also needs clear authority to initiate enforcement against parties acting on behalf of a certifying agent (e.g., a subcontractor) or individual certification offices. The use of subcontractors is common in the organic industry and effective enforcement depends on oversight of all persons involved in the certification of organic operations. Uncertainty about whether AMS can target a certification office or contractor for

⁴⁰ See section 10104(d) of the Agriculture Improvement Act of 2018, Public Law No: 115-334, available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf> (7 U.S.C. 6515(j)).

enforcement action interferes with precise and expedited enforcement. Therefore, AMS revised the organic regulations to clarify that entities acting on behalf of a certifying agent are subject to oversight and enforcement.

90-Day notification of new certification offices

To support the consistent application of the organic regulations across all certifying agents, § 205.501(a)(22) requires certifying agents to notify AMS within 90 calendar days of the opening of any office performing certification activities. A *certification office* is defined as any site or facility where certification activities take place, except for activities that take place at certified operations or other specialized facilities, such as inspection, sampling, and testing. This notification requirement applies to any facility or location that meets the definition of certification office, regardless of how the office is classified by a certifying agent (e.g., “central” vs. “satellite” offices).

Notification of a new office opening must include basic information to support effective oversight of the certification office, including the countries serviced, location and nature of the certification activities, and the qualifications of the personnel that will provide the certification activities. Information on the location of new offices allows AMS to efficiently use personnel and travel resources to schedule on-site audits, and to be precise in any adverse action that may affect only a portion of certifying agent’s accreditation, e.g., a certification office or activities in a specific country or region. Information on the types of certification activities being conducted allows AMS to better evaluate the need for additional oversight; for instance, a new office located in a high-risk area with a history of organic fraud may require additional oversight.

Authority to issue notices of noncompliance

AMS is clarifying its authority to issue notices of noncompliance to certifying agents based on the activities of persons acting on behalf of a certifying agent, the activities of a certification office, or the activities in a specific country. AMS added the term

certification activity to § 205.2 of the organic regulations to define activities that are essential to the function of a certifying agent and therefore subject to NOP oversight. *Certification activity* is any business conducted by a certifying agent, or by a person acting on behalf of a certifying agent (e.g., a specific office operating in specific countries, or a subcontractor or subcontractor organization). Any business activity conducted by a certifying agent as it implements the USDA organic regulations is considered a certification activity, including review, inspection, and certification of organic operations. The definition includes a non-exhaustive list of certification activities that fall under AMS oversight authority.

AMS's authority to initiate enforcement action for a portion of a certifying agent's operation is reinforced in § 205.665(a)(1). This states that AMS may send notifications of noncompliance to a certifying agent based upon review of the certification activities of:

- A person acting on behalf of the certifying agent or
- A certification office.

This means that AMS may issue notices of noncompliance to a certifying agent based on the activity of certifying agent subcontractors, or an individual certification office(s) that may be in a different location from the certifying agent's main office. Further, AMS may suspend or revoke a portion of accreditation for activities in a specific certification office, country, or region.

Summary of changes to the final rule

AMS made no changes to the proposed regulatory text in §§ 205.2, 205.501(a)(22), and 205.665(a) with respect to oversight of certification activities and has finalized the proposed requirements.

Summary of public comment

The majority of public comments supported AMS's proposed clarification. Commenters were primarily concerned that the proposed definition of certification office would subject remote staff and home offices to NOP audits. Commenters stated that NOP audits of home offices and remote workers does not align with NOP's intent for adding the term certification office. Comments suggested excluding home offices and telework locations from the definition for certification office, and some explained that certifying offices which solely operate virtually should qualify as a certification office and individual workers working remotely on a temporary basis should not be subject to NOP audits.

Commenters were also concerned that the 90-day timeframe for certifying agents to notify AMS of new offices conducting certification activities is too long.

Responses to public comment

Definition of certification office

(Comment) AMS received comments requesting that the definition of *certification office* exclude home offices and remote workers. Commenters asserted that if home offices for remote staff are included in the definition of certification offices, they will be subject to audits, which would be unreasonable.

(Response) Home offices are not excluded in the definition of *certification office* because some certifying agents may maintain home offices as their primary location or certification office from which they conduct certification activities.

90-day notification of new offices

(Comment) We received comments stating that the 90-day timeframe for certifying agents to notify AMS of new offices conducting certification activities is too long. Some suggested that timeframes of 30 or 45 days would be more appropriate.

(Response) The 2018 Farm Bill established the 90-day timeframe. Section 10104 (j) of the 2018 Farm Bill and 7 U.S.C. 6515(j) state “Not later than 90 days after the date on which a new certifying office performing certification activities opens, an accredited certifying agent shall notify the Secretary of the opening.” While certifying agents may choose to notify AMS earlier, AMS is retaining the 90-day notification requirement in the organic regulations.

(Comment) Commenters asked what office types (e.g., satellite offices or main offices) would require a certifying agent to notify AMS.

(Response) Certifying agents must notify AMS of the opening of any type of office where certification activities take place. This requirement for notification is based on the activities of an office not the type.

J. Accepting Foreign Conformity Assessment Systems.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.2	Terms defined. Definitions for <i>Conformity assessment system</i> and <i>Technical requirements</i> .
205.511	Accepting foreign conformity assessment systems. Entire section.

AMS has added a new section to the USDA organic regulations, § 205.511, on accepting foreign conformity assessment systems that oversee organic certification in foreign countries. Section 205.511 replaces former § 205.500(c).

Affected entities may include, but are not limited to:

- Trade partners who have established an organic equivalence determination or are interested in establishing an equivalence determination with the United States.
- Foreign certifying agents and certified operations not accredited or certified by the USDA

- Foreign organic producers who export products to the United States

The above list is a general description of entities likely to be affected by this action. Other types of entities could also be affected. You should carefully examine the regulatory text to determine if you or your organization may be affected by this action.

Background

The OFPA, under 7 U.S.C. 6505(b), allows imported organic products to be sold or labeled in the United States as organically produced if the Secretary determines that the products have been produced and handled under an organic certification program with requirements and oversight determined to be at least equivalent to those described in the OFPA. Under this authority, the U.S. government, including the USDA and the U.S. Trade Representative, work closely together to implement processes that determine the equivalence of foreign organic certification programs and then negotiate an arrangement or agreement as appropriate.

USDA organic regulations formerly addressed USDA's authority to make equivalence determinations in general terms under § 205.500(c), but did not describe the criteria, scope, and other parameters to establish, oversee, or terminate such equivalence determinations, which are critical to the enforcement of organic imports. This new § 205.511 does not change current policy or add any new requirements. It codifies existing practices and clarifies the procedures followed when determining organic equivalence, which strengthens oversight and enforcement capacity of organic imports by supporting the government's authority to reassess, continue, and terminate equivalence determinations, as necessary. Without this clear implementation of Federal authority in the USDA organic regulations, the government could face challenges establishing and enforcing terms under current and future equivalence determinations that are critical to ensuring the integrity of imported organic products.

Definitions

The rulemaking adds two new terms in § 205.2: *conformity assessment system* and *technical requirements*. These terms are defined to ensure that the process and requirements described in § 205.511 are clear. The rulemaking defines *conformity assessment system* as all activities, including oversight, accreditation, compliance review, and enforcement, undertaken by a government to ensure that the applicable technical requirements for the production and handling of organic agricultural products are fully and consistently applied. The rulemaking defines *technical requirements* as a system of relevant laws, regulations, regulatory practices, standards, policies, and procedures that address the certification, production, and handling of organic agricultural products.

Foreign product certification

Section 205.511(a) describes the U.S. government's authority under OFPA to make equivalence determinations and explains the conditions in which foreign-produced product can be labeled and sold as organic in the United States.

Equivalency determination request

Section 205.511(b) describes the process used by the U.S. government and other foreign governments for initiating a request for an equivalence determination. Since there are several factors that may impact whether the U.S. government moves forward to review an equivalence determination request (e.g., agency resources, capacity to oversee the potential trade arrangement or agreement, relative benefits for the U.S. organic sector), this section clarifies that the U.S. government will determine if it can proceed with the evaluation process on a case-by-case basis.

Equivalency reviews and reassessments

Section 205.511(d) lays out the current process that AMS and other foreign governments use to monitor equivalence determinations that have been made. The section provides some flexibility in the timing of reviews to accommodate unavoidable

factors in both countries that can impact timing (e.g., federal budgets, election cycles, growing seasons).

Equivalence termination procedures

Section 205.511(e) describes the conditions under which the U.S. government may terminate equivalence determinations. These conditions for termination are commonly accepted among countries that maintain equivalence determinations and are based upon the core concepts underlying equivalence. The U.S. government must be able to terminate equivalence determinations under these conditions in order to fulfill its statutory obligation to assure that organic products sold in the United States are compliant with OFPA and the USDA organic regulations and maintain a level playing field for U.S. farms and businesses.

In addition to the conditions described in § 205.511(e), the U.S. government may also terminate an equivalence determination “for other good cause.” This includes risks that may negatively affect the integrity of organic products imported from a country with which the U.S. government has an equivalence determination, policy changes, or resource constraints that impact either government. Examples include:

- Repeated cases of organic fraud that are not corrected by a foreign government;
- Increasing levels of organic fraud that a foreign government is unable or unwilling to address;
- Political instability, safety concerns, or limitations on access that make it impossible for USDA to travel to and assess a foreign government’s equivalence determination;
- Reduction in funding or other resources that compromises a foreign government’s or USDA’s ability to operate its organic program and oversee the equivalence determination; or

- Changes in a foreign government’s unilateral equivalence determination with the USDA that may restrict domestic producers’ access to foreign markets.

In all cases, the U.S. government would provide notice and justification to the foreign government prior to termination, and give notice to affected organic stakeholders along with a reasonable timeline to transition.

Summary of changes to the final rule

AMS made several revisions to the proposed regulatory text when writing this final rule. Changes to the proposed rule are discussed below and are followed by responses to specific themes from public comment.

- AMS added “oversight, accreditation, compliance review, and enforcement” to the definition of *conformity assessment system* to clarify the scope of the assessment of a foreign organic certification system’s eligibility for an equivalence determination.
- AMS added “standards, policies” and “certification” to the definition of *technical requirements* to clarify the scope of this term and to ensure that the definition covers all parts of a country’s framework for regulating organic products.
- AMS corrected the syntax of § 205.511(a) and (b) to state that foreign product “may be sold, labeled, or represented in the United States as organically produced.” This accurately reflects the intent to allow foreign organic product to be exported to the United States and sold as organic, but does not allow foreign organic product to be labeled as domestically produced in the United States.
- AMS removed the reference to a two-year review cycle in § 205.511(d) and replaced with a statement explaining how AMS will determine the timing and scope of reviews of equivalence determinations. This gives AMS the flexibility to determine timelines for audits and reassessments of equivalence

determinations, and allows AMS to accommodate unavoidable factors when scheduling audits and reassessments of equivalence determinations.

Summary of public comment

Public comments showed overall support for codifying AMS's existing practices for determining organic equivalence, agreeing that the proposed updates would strengthen the integrity of imported organic products.

Several of these comments largely focused on how the specifics of the proposed § 205.511 would improve the transparency and oversight of equivalence determinations and recognition agreements. Some of these comments recommended requiring certified foreign operations to be listed in the Organic Integrity Database and for NOP to investigate any countries with equivalence determinations found to be noncompliant. Some comments expressed opinions in opposition to some existing trade arrangements, and/or suggested that USDA not allow equivalence determinations and require direct certification via USDA-accredited certifying agents instead. Some comments were also uncertain the proposed requirements of § 205.511 apply to recognition agreements.

Several comments expressed concern that the proposed § 205.511(a) and (b) would allow organic products produced under foreign equivalence determinations to be sold as “produced in the United States.” Some comments pointed out that the two and five-year inspection timelines may conflict with other regulations.

Responses to public comment

Definition of conformity assessment systems

(Comment) AMS received comments requesting that several activities be included in the definition of *conformity assessment systems*. Commenters stated that it is critical to ensure that foreign governments have sufficient oversight, accreditation, compliance, and enforcement mechanisms in place to ensure that organic technical requirements are being enforced.

(Response) The definition of *conformity assessment systems* has been modified from the proposed rule to include the following activities: oversight, accreditation, compliance review, and enforcement. The additional activities were added to the definition of *conformity assessment systems* to clarify the scope of the assessment of a foreign organic certification system's eligibility for an equivalence determination.

Definition of technical requirements

(Comment) We received comments requesting that the definition of *technical requirements* include the terms standards, policies, and certification. Commenters stated that it was important that these terms be added to ensure that the definition covers all parts of a country's framework for regulating organic products.

(Response) The terms standards, policies, and certification have been added to the definition of *technical requirements*. The new terms were added to ensure that the definition covers all parts of a country's framework for regulating organic products.

Labeling of foreign product origin

(Comment) Comments noted that § 205.511(a) could be interpreted to allow labeling of foreign-produced organic product as "produced in the United States."

(Response) The final rule corrects the syntax of § 205.511(a) to state foreign organic product "...may be sold, labeled, or represented in the United States as organically produced." This accurately reflects the intent to allow foreign organic product to be exported to the United States and sold as organic, but does not allow foreign organic product to be labeled as domestically produced in the United States.

Equivalence reviews and reassessments

(Comment) We received comments requesting AMS clarify its timeline for audits and reassessments of equivalence determinations. Additionally, commenters noted the difference between proposed § 205.511(d), which requires a two-year midcycle review,

and the proposed rule preamble, which states, “The review cycles mirror ISO standards, which include a five-year reassessment cycle and mid-cycle reviews.”

(Response) The final rule has been revised to allow AMS additional flexibility to determine timelines for audits and reassessments of equivalence determinations. The final rule replaces “two-year cycle” and “five years” with the phrase “regular reviews and reassessments.” The new regulatory language allows AMS to accommodate unavoidable factors when scheduling audits and reassessments of equivalence determinations.

(Comment) AMS received comments asking if recognition agreements would be subject to AMS audits and reassessments per new § 205.511.

(Response) Recognition agreements will be subject to AMS audits and reassessments of equivalence per § 205.511.

Equivalence determination procedures

(Comment) We received comments requesting AMS describe in § 205.511(e) the criteria used to determine termination of an equivalence determination.

(Response) Each equivalence determination is unique and is assessed using the general criteria described in § 205.511. To ensure fair assessment of each unique equivalence determination, AMS has not codified specific criteria used to determine termination of equivalence.

K. Compliance and Noncompliance Procedures.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.660	General. Paragraph (c).
205.661	Investigation. Change section heading only.
205.100	What has to be certified. Paragraph (c).

205.662	Noncompliance procedure for certified operations. Paragraphs (e)(3), (f)(1), and (g)(1).
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Authority to pursue enforcement action against any OFPA violator

The NOP currently pursues enforcement actions against uncertified parties when AMS has evidence of OFPA violations. In 2021, more than half of the complaints received by the NOP alleging violations of OFPA involved uncertified operations representing products as organic. Continued AMS enforcement against uncertified operations is central to the effective administration of the OFPA.

The rulemaking updates the USDA organic regulations by adding new paragraph (c) to § 205.660, to clarify that the NOP Program Manager may initiate an enforcement action against any violator of OFPA, regardless of certification status. Consistent with the new paragraph (c) to § 205.660, to clarify that the NOP Program Manager may initiate an enforcement action against any violator of the OFPA, AMS changed the title of § 205.661 from “Investigation of Certified Operations” to “Investigation.”

Enforcement action against responsibly connected persons

Person(s) responsibly connected to a violator of the OFPA may be complicit in the OFPA violation(s) because of their association to the violator. Because of this, the rulemaking clarifies at §§ 205.100 and 205.662 that any person who is responsibly connected to an operation that violates OFPA or the USDA organic regulations may be subject to a suspension of certification, civil penalties, or criminal charges and/or may be ineligible to receive certification. This clarification strengthens AMS’s enforcement capacity by ensuring that enforcement actions and penalties for violations of the OFPA extend to all accountable parties.

Responsibly connected persons who are suspended or revoked may request to have their certification reinstated, if suspended, or their eligibility to become certified reinstated, if revoked. AMS has published guidance for Reinstating Suspended

Operations (NOP 2605), which applies to both suspended and revoked operations that want to become certified again.⁴¹

Timely updates to the Organic Integrity Database

Timely updates to the Organic Integrity Database (OID) are critical to inform other certifying agents, operations in the supply chain, and consumers when an operation is no longer certified and can help prevent noncompliant products from entering or continuing in the stream of commerce. At § 205.662(e)(3) of the regulations, AMS requires certifying agents to provide timely updates on the status of an operation that has been suspended or revoked (or that has surrendered its organic certification). These updates should be viewable in the Organic Integrity Database within three business days of issuing a notification of suspension or revocation, or from the effective date of a surrender. This publicly available information helps businesses in the supply chain confirm that an operation from which they purchase or receive organic products has a valid organic certification.

In most cases, the effective date of an operation's surrender means that the certifying agent has received notification from the operation and confirmed the surrender status. AMS recognizes that in some cases the effective date of the surrender may date prior to certifying agent confirmation of surrender and the Organic Integrity database updates will extend past the three-day window.

Federal civil penalty inflation adjustment

Finally, AMS amended § 205.662(g)(1) of the regulations to update the citation which specifies the maximum civil penalty amount for violations of the OFPA. Title 7 CFR 3.91(b)(1)(xxxvi) provides the civil penalty amount for each violation of OFPA.

⁴¹ Instruction NOP 2605, Reinstating Suspended Operations:
<https://www.ams.usda.gov/sites/default/files/media/2605.pdf>

This amendment aligns with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114-74, sec. 701.⁴²

Changes from proposed to final rule

AMS made one change to the proposed regulatory text when writing this final rule:

- Removed the phrase “directly or indirectly” from 205.660(c) because its meaning was confusing. The intent of 205.660(c) is to clarify the scope of potential enforcement actions which may include blatant and subtle false labeling and representation of nonorganic products as organic.

No other changes were made to the proposed regulatory text in §§ 205.100(c), 205.660(c), 205.662(e)(3)), and 205.662(f)(1) and AMS has finalized the proposed requirements with respect to AMS’s authority to enforce against any OFPA violator and all responsibly connected persons connected to a violator. AMS also made no changes to proposed requirement to timely update the Organic Integrity Database.

Summary of public comments

In general, most public comments supported the proposed revisions to clarify AMS’s authority to enforce against any violator of the OFPA and the organic regulations. Many comments also discussed the revisions in detail and offered recommendations or changes to the proposed policy.

Many comments discussed the proposed three-day timeframe to submit updates to the Organic Integrity Database (§ 205.662(e)(3)). Some comments describe the requirement as too burdensome, while some support the three-day timeframe. Comments opposing the proposed requirement recommended alternatives ranging from 7 to 30 days.

⁴² <https://www.govinfo.gov/content/pkg/PLAW-114publ74/html/PLAW-114publ74.htm>. As of the publication of this rule the civil penalty amount is \$20,130 per violation of OFPA occurring on or after February 15, 2022. The civil penalty amount will be adjusted in the future so readers should refer to 7 CFR 3.91(b)(1)(xxxvi) for the current amount.

Other comments state that updates should be immediate, or made within 48 hours, so that noncompliant products do not continue in the stream of commerce.

Several comments also claim that identifying and tracking all responsibly connected persons would be difficult, and requested more guidance on how this should be done. A few comments asked AMS if revocation of an operation's certification should also result in the revocation of all responsibly connected persons' certification.

Some comments also asked AMS to clarify the phrase "or submit a request for eligibility to be certified" in § 205.662(f)(1). A few comments also asked if this applies to persons responsibly connected to a suspended operation. One comment also asked if this section applies to revocation of certification.

Responses to public comment

Timely updates to the Organic Integrity Database

(Comment) AMS received comments that the three-day requirement to update the Organic Integrity Database is too burdensome. Commenters did not quantify negative impacts to certifying agents, nor did they clearly explain why this would be burdensome for certifying agents. Others supported the three-day timeframe or recommended that updates should be immediate or within 48 hours, so that noncompliant products do not continue in the stream of commerce. Other commenters recommended alternatives ranging from 7 to 30 days.

(Response) Certifying agents will have a one-year implementation period before this requirement takes effect. During the implementation period, there is no fixed time frame for updating data in the Organic Integrity Database. This requirement is limited in scope and applies when an operation is suspended, revoked, or has surrendered organic certification. Public accessibility of an operation's correct certification status is essential for movement of products in organic supply chains. AMS believes that three days for certification status updates is adequate and supports organic verification across supply

chains of different speeds. Extending the deadline beyond three days may interfere with the timely verification of an operation's accurate certification status. This is critical data and inaccurate information can delay legitimate transactions and fail to prevent sales of products from suspended or revoked operations. Further, AMS provides certifying agents with an API to upload data to the Organic Integrity Database, which reduces redundant or duplicative work for certifying agents.

Enforcing against responsibly connected persons

(Comment) AMS received comments stating that identifying and tracking all responsibly connected persons would be difficult because these entities are not listed in the Organic Integrity Database. Commenters requested guidance on how this should be accomplished.

(Response) AMS is not specifying how certifying agents must identify responsibly connected persons, nor are we requiring responsibly connected persons to be listed and searchable as such in the Organic Integrity Database. Obtaining responsibly connected persons from organic system plans and/or identifying all known responsibly connected persons in adverse action letters are best practices that certifying agents should pursue.

Use of term "indirectly" in 205.660(c)

(Comment) Commenters requested clarification of what is meant by a label or information which "indirectly" implies that product was produced with organic methods if product was produced in violation of the OFPA or the organic regulations.

(Response) AMS removed the phrase "directly or indirectly" from 205.660(c) because its meaning was confusing. The intent of 205.660(c) is to clarify the scope of potential enforcement actions which may include blatant and subtle false labeling and representation of nonorganic products as organic.

Civil penalty citation

(Comment) For civil penalty fines, commenters requested AMS cite the regulation, not the amount, since the latter changes and becomes outdated.

(Response) The proposed and final rules cite the regulation that sets the civil penalty amount.

Documented delivery confirmation

(Comment) Commenters requested AMS allow “documented delivery confirmation” to accommodate electronic communication rather than only certified paper mail.

(Response) AMS accepts that “dated return receipts,” which are required when certifying agents or NOP sends an adverse action notice to an operation, may include electronic communications. This means that the adverse action notices may be sent electronically to the recipient and delivery confirmation may include, for example, confirmation that an email has been delivered.

I. Mediation

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.504	Evidence of expertise and ability. Introductory text and paragraph (b)(8).
205.663	Mediation. Entire section.

Background

AMS revised § 205.663 to improve the general readability of this section and to more clearly explain how mediation may be used in noncompliance procedures. When successful, mediation is an efficient way to bring operations into compliance and resolve conflicts among certifying agents and operations. The USDA organic regulations require that certifying agents and State organic programs provide applicants for certification and

certified operations the right to request mediation when they issue a denial of certification, notice of proposed suspension, or proposed revocation of certification (§§ 205.405(d) and 205.662(c)). Section 205.663 provides requirements for requesting mediation, responding to a mediation request, the time frame for reaching an agreement, and what happens when mediation is unsuccessful.

The USDA organic regulations require certifying agents and State organic programs to notify operations of the option to request mediation as an alternative dispute resolution to resolve noncompliance findings that have led to a proposed suspension, revocation, or denial of certification. This will facilitate resolution of these issues before they escalate to an appeal to AMS or a State organic program.

Mediation is a collaborative process

The requirements for mediation support a process that is efficient and accessible to producers and handlers who want to resolve a denial of certification, proposed suspension, or revocation of certification. Mediation is a collaborative process between a certifying agent and an operation or applicant for certification. A successful mediation addresses the noncompliance(s) and leads to full compliance with the USDA organic regulations. To ensure that mediation is readily accessible, certifying agents and certified operations or applicants may engage in mediation without a third-party mediator, provided that all parties agree upon the person who will serve as the mediator.

Mediation must be requested in writing

After a certifying agent issues a denial of certification, proposed suspension, or revocation of certification, a certified operation and certifying agent may discuss the option of mediation prior to receiving a request for mediation. However, for mediation to proceed as a form of alternative dispute resolution, an operation must request mediation in writing to the certifying agent. The request for mediation must be submitted to the certifying agent within 30 calendar days from the date of the proposed adverse action or

denial of certification (§ 205.663(b)(1)). This aligns with the length of time provided to submit an appeal of a proposed adverse action.

Mediation acceptance criteria

A certifying agent determines whether to accept or reject a written request for mediation. Certifying agents must include mediation acceptance decision criteria as part of the administrative policies and procedures which certifying agents are required to submit to demonstrate their ability to comply with the certification program (§ 205.504(b)(8)). The mediation acceptance criteria must be fair and reasonable and not arbitrary. The criteria must be based on factors that will likely determine potential success or failure of the mediation process. The certifying agent must document how it applied the criteria to accept or reject requests for mediation. Parties to the mediation may develop conditions, such as cost, timeframes to reach a settlement agreement within the allowed maximum of 30 days, and any incremental steps, only after a certifying agent accepts a mediation request. A certifying agent must not impose any preconditions for the acceptance of mediation (i.e., the certifying agent cannot require that the operation take a specific action—other than submitting a written request for mediation—before it will consider mediation).

If a certifying agent decides to reject a request for mediation, based on its criteria for acceptance of mediation, it must inform the operation in writing, with the justification for the rejection. That notification must explain that the operation has the right to appeal the rejection of mediation (§ 205.663(b)(3)). While an operation appeals a rejection of mediation, the proposed suspension or revocation which led to the request for mediation must not be finalized (§ 205.663(b)(4)). The date that the notification is received by the operation is important because it starts the 30-day window for filing an appeal and may be used to determine whether an appeal has been timely filed. Likewise, when mediation is unsuccessful, the certifying agent must inform the operation in writing to document the

start of the 30-day window for filing an appeal. This means that certifying agents must send rejection and termination of mediation notices using a method with delivery confirmation.

Use of settlement agreements

In accepting mediation, a certifying agent may also, at its discretion, offer a settlement agreement for an operation to consider (§ 205.663(e)). The outcome of successful mediation is a settlement agreement that brings an operation into compliance with the USDA organic regulations. A settlement agreement must clearly describe the corrective actions and timeframes for implementing corrective actions, and may impose additional actions (e.g., unannounced inspections, sampling for residue testing) to ensure the operation maintains compliance. A settlement agreement may also include a suspension of organic certification.

A settlement offer may be useful when the corrective action(s) is clear and the noncompliance(s) is not recurrent. As part of the mediation, an operation may accept or reject the settlement agreement, negotiate the terms with the certifying agent, or request a mediator to try and reach a settlement agreement.

Use of a third-party mediator

This rule clarifies that mediation does not require a third-party mediator to reach a settlement agreement (§ 205.663(c)). The certifying agent and operation may agree that mediation will be between only those two parties. For example, mediation may consist of a phone call or series of phone calls between the operation and the certifying agent to discuss the terms of a settlement offer prior to signing the agreement.

In some cases, the use of a third-party mediator may be appropriate, either because the operation initially requested this, or the operation rejected a settlement offer and then requested a mediator. To demonstrate their ability to comply with the certification program, each certifying agent must submit a process to identify a qualified mediator and

set the time and location of mediation session(s), mediation format (in-person, video, phone), and mediation fees and payment (§ 205.504(b)(8)).

Role of the Program Manager

The Program Manager does not require, manage, or otherwise participate in mediation between operations and certifying agents or State organic programs. The Program Manager may review an agreement that results from the mediation for conformity to the OFPA and the USDA organic regulations and reject any nonconforming provision or agreement (§ 205.663(f)). The Program Manager may direct the certifying agent or State organic program to revise any nonconforming provisions, and the operation would have a new opportunity to accept or reject the revised settlement agreement.

Mediation under the USDA organic regulations is an alternative dispute resolution mechanism, conducted between a certified operation or applicant for certification and a certifying agent or State organic program. The Program Manager is not involved in determining the outcome of a mediation, notwithstanding his or her authority to review dispute resolution terms for conformity with the OFPA and the USDA organic regulations.

This does not affect AMS's ability to carry out oversight, compliance, and enforcement activities on behalf of the Program Manager. For example, AMS may conduct informal mediation, at its discretion, and enter into mutually agreeable settlement agreements with parties that receive a proposed adverse action (§ 205.663(g)).

Changes from proposed to final rule

AMS made minor revisions to the proposed regulatory text when writing this final rule. Changes to the final rule are discussed below and are followed by specific themes from public comment.

- AMS added the words “of receipt” to § 205.663(b)(3) and (e) so that the 30-day time frame for requesting an appeal when mediation is rejected or terminated provides adequate due process and aligns with the appeal filing time frame for other adverse action notices.
- AMS added a requirement for termination of mediation to be documented in a written notice so it is clear when an operation may exercise its right to file an appeal.
- AMS revised the introductory paragraph at § 205.504 to include the cross-reference to § 205.663 because certifying agents must submit mediation procedures as part of the evidence of their ability to comply with and implement mediation requirements.
- AMS relocated the requirement to submit mediation policies and procedures from § 205.663(a) to § 205.504(b), where requirements for certifying agents’ policies and procedures are identified.
- AMS added a requirement that certifiers document the reason for denying mediation. If the rejection is appealed, this will allow the Administrator to determine whether the rejection was reasonable and consistent with the certifier’s criteria for rejection.
- AMS added the word “reasonable” to § 205.504(b)(8) to describe parameters for the criteria that certifiers must set for accepting mediation. This supports fair and consistent decisions on requests for mediation across certifying agents.
- AMS revised § 205.663(e) to require that a settlement agreement be reached within 30 days from the start of mediation. This clarifies when the 30-day timeframe begins and supports timely resolution of compliance issues.
- AMS added a new provision at § 205.663(b)(4) to clarify that an adverse action (e.g., proposed suspension or revocation) must not be finalized during the appeal

proceeding. This clarification supports the right to adequate due process before an adverse action takes effect.

Responses to public comment

Settlement agreements

(Comment) Several commenters asked questions about the management of settlement agreements.

(Response) AMS is not addressing questions about management of settlement agreements in this rule because they are beyond the scope of this rule. More information on settlement agreements is available through the Organic Integrity Learning Center and annual training for certifying agents.

Mediation

(Comment) AMS received a comment stating certifying agents should be allowed to propose mediation and offer settlement agreements.

(Response) The regulations do not prohibit a certifying agent from informing an operation of its willingness to engage in mediation prior to an operation requesting mediation. In addition, the regulations do not prohibit a certifying agent from offering a settlement agreement as part of mediation to resolve an adverse action.

(Comment) AMS received a comment to replace the terms “mediation session” with “mediation” to allow informal mediation at § 205.663(e).

(Response) AMS replaced “mediation session” with “mediation” to account for informal mediation which may not use the same format as formal mediation.

(Comment) AMS received a comment to change the deadline to submit a request for mediation from “30 days from receipt” to “30 days from date of issue.”

(Response) AMS is declining to make this change, in order to align with USDA’s Office of Administrative Hearings and Appeals, which uses date of receipt and not date of issue. This practice preserves due process rights of operations being notified of adverse actions.

AMS believes that the use of electronic communications and the availability of electronic delivery confirmation will make this requirement less burdensome.

(Comment) Comments requested that AMS align language for timeframes for requesting mediation and requesting an appeal.

(Response) AMS agrees that the timeframes for requesting mediation and requesting an appeal when mediation fails should be consistent. We changed § 205.663(b)(3) to state that an operation has 30 days from receipt of the rejection of request for mediation to file an appeal. We also changed § 205.663(e) to state that an operation has 30 days from receipt of a written notice of termination of mediation to file an appeal. These changes make the timeframes to file an appeal consistent whether mediation is rejected or terminated.

(Comment) AMS received a comment that both parties agreeing on the person conducting mediation should only apply to formal mediation.

(Response) AMS disagrees that consensus on the person conducting mediation should only apply for formal mediation. Informal mediation also requires that parties agree on who will facilitate the mediation, even when the parties to the mediation facilitate the process themselves.

M. Adverse Action Appeal Process

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.2	Terms defined. Definition for <i>Adverse action</i> .
205.680	Adverse Action Appeal Process—General. Entire section.
205.68	Adverse Action Appeal Process—Appeals. Paragraphs (a), (a)(2), (b), (c), and (d)(1) and (2).

General appeals

AMS revised parts of the adverse action appeals process in §§ 205.680 and 205.681. These changes clarify which actions can be appealed, recognize the use of alternative dispute resolution in lieu of a formal administrative proceeding to resolve an appeal, and reinforce that appeal submissions need to comply with the basic requirements in the regulations.

The OFPA calls for an expedited appeals procedure that gives persons affected by a proposed adverse action the opportunity to appeal that action (7 U.S.C. 6520). All appealed adverse actions are expeditiously reviewed and decided in an unbiased manner by persons that are not involved in the initial decision to issue an adverse action. In December 2014, AMS issued guidance to explain how it administers the adverse action appeal process, the status of an appellant during an appeal, and the possible outcomes of an appeal in NOP 4011, Adverse Action Appeal Process.⁴³

The original USDA organic regulations described how certified operations, accredited certifying agents, and applicants for certification or accreditation may appeal a noncompliance decision that would affect their certification or accreditation status or eligibility to become certified or accredited (§ 205.680(a)). The regulations explained when an appeal may be submitted, how it must be submitted, and what the appeal submission must contain. Specifically, appeals of noncompliance decisions of a certifying agent or NOP are appealable to the AMS Administrator, or to the State organic program if the appellant is in a State with an approved State organic program. A decision to sustain an appeal will result in a favorable action with respect to the appellant's certification or accreditation. Following a decision to deny an appeal, AMS will initiate a formal administrative proceeding (i.e., a hearing), unless the parties resolve the issue

⁴³ NOP 4011, Adverse Action Appeal Process. December 23, 2011: <https://www.ams.usda.gov/sites/default/files/media/4011.pdf>

through settlement, or the appellant waives the hearing. If an appeal is not timely filed, the adverse action which led to the appeal will be final and cannot be appealed further.

Adverse action defined

The new term *adverse action* clarifies which actions may be appealed under the USDA organic regulations. *Adverse action* replaces the use of “noncompliance decision” throughout this section. *Adverse action* is defined as a noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease-and-desist notice; or a civil penalty.

Option to request mediation or appeal of an adverse action issued by a certifying agent or State organic program

When a certifying agent or State organic program issues a proposed suspension or revocation, operations have the option to request mediation or appeal the proposed adverse action. Mediation is covered in more detail in § 205.663. The mediation process can be a viable path to resolve noncompliances that are correctable and are not willful or recurrent. If mediation is rejected or is not successful, the operation maintains the right to appeal. The time frame for filing an appeal is calculated from receipt of the notice of rejection or termination of mediation (§ 205.663(b)(3) and (e)).

Administrative requirements

Appeals must be properly filed as described in paragraphs (c) and (d) of § 205.681.

This means that an appeal must be:

- Filed in writing within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later
- Sent to the correct physical or email address:
 - 1400 Independence Ave., S.W., Room 2642, Stop 0268, Washington, D.C.

- NOPAppeals@usda.gov
- Include a copy of the adverse action and explain why the adverse action is incorrect.

An adverse action will become final and nonappealable unless an appeal is timely filed. Appeals will be considered “filed” on the date received by the Administrator or by the State organic program.

Denied appeals

AMS supports the use of alternative means, such as mediation and settlement agreements to expedite resolution of an adverse action dispute while preserving due process and avoiding prolonged formal proceedings. When an appeal is denied, AMS offers the appellant the option to waive further hearing. When an appellant waives a hearing, the appeal decision is final and takes effect. Failing to timely submit a request for hearing is regarded as a waiver of hearing. In some cases, when an appeal is denied, AMS may pursue a settlement agreement in lieu of initiating a formal administrative proceeding. AMS assesses the potential for a settlement agreement on a case-by-case basis and will exercise this option when a settlement may offer a viable route for the operation to come back into compliance or to exit the organic sector. Even when an appellant requests a hearing, AMS and the appellant may enter into a settlement agreement prior to the hearing. This provides flexibility to resolve appeals outside of a lengthy formal administrative process. The appellant reserves the right to an administrative hearing. Entering into a settlement agreement is an optional, not compulsory, alternative to a hearing.

Changes from proposed to final rule

AMS made several revisions to the proposed regulatory text when writing this final rule, including revising § 205.681(a)(2) and (b)(2) to state that the Administrator will initiate a formal proceeding and identify the conditions when that would not occur, i.e.,

the parties settle beforehand, or the appellant waives its right to a hearing. These sections explain that failing to timely request a hearing constitutes a waiver of hearing. AMS also deleted “policies and procedures” from 205.681(d)(3) to clarify that the USDA organic regulations are the basis for enforcement.

Summary of public comments

Comments were generally supportive of the clarifications to the appeals sections of the USDA organic regulations. The main concern in comments was the revision to state that AMS “may” rather than “will” initiate a formal administrative proceeding if the Administrator denies an appeal. The comments stated that this change removes due process rights of an appellant and should not be at the discretion of AMS. Other comments requested changes to appeal filing timeframes and delivery confirmation.

Responses to public comment

(Comment) Comments opposed the change to not require AMS to initiate the hearing process following an appeal denial.

(Response) AMS made changes to § 205.681(a)(2) and (b)(2) to state that AMS will begin formal administrative proceedings once an appeal is denied. Those sections also explain that an administrative proceeding would not begin if the appellant waives or fails to timely request a hearing or AMS and the appellant reach a settlement agreement. This revision does not change AMS’s intent that appellants always have the right to request a hearing following a denial of an appeal; it only provides options for a more expedient resolution in lieu of a hearing if the appellant consents to that outcome.

(Comment) AMS received comments stating that the proposed revisions to § 205.681(b) do not clearly provide appeal rights for certifying agents.

(Response) *Person*, as defined in the regulations at § 205.2, includes certifying agents and § 205.681(b) allows persons to appeal an adverse action by the NOP Program

Manager. Further, § 205.681(b)(1) explains what happens to accreditation when an appeal is sustained.

(Comment) AMS received comments suggesting that dated return receipts should be replaced with documented delivery confirmation.

(Response) AMS interprets dated return receipts to include electronic confirmation of electronic delivery, such as registered email which shows that a message has been delivered to recipient's email and the date of delivery.

(Comment) AMS received comments that appeals should be filed within 30 days of date of notice rather than date of receipt of notice.

(Response) AMS is not making this change because it could interfere with due process rights of an appellant. We believe that appellant should have the full 30 days to appeal from the time that they receive the notice and not lose time due to possible delays in the mail or delivery service. Therefore, we are keeping this timeframe to 30 days from the date of receipt of notice to ensure that appellants have 30 days to review the notice and to decide how to respond.

(Comment) Comments requested that NOP timely respond to appeals because operations are allowed to remain certified during the appeal process and any subsequent hearing proceeding.

(Response) AMS has procedures to thoroughly and efficiently evaluate NOP appeals. AMS generally resolves appeals within 6 months of receipt. AMS also frequently uses settlement agreements to resolve appeals which decreases the number of appeals that may potentially proceed to a hearing.

N. Producer Group Operations.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.2	Terms defined.

	Definitions for <i>Producer group member</i> , <i>Producer group operation</i> , <i>Producer group production unit</i> , and <i>Internal control system</i> .
205.201	Organic production and handling system plan. Paragraph (c).
205.400	General requirements for certification. Paragraph (g).
205.403	On-site inspections. Paragraph (a)(2).

The organic industry has a longstanding practice of certifying groups of producers. This practice helps small farmers access the organic market and enables handlers to source products that are not produced in the United States. Compared with traditional producers and handlers, these groups of producers have unique needs in quality control and compliance. AMS is establishing requirements for producer group operations that promote consistent certification practices and ensure their continued viability and integrity. This rule codifies key provisions of the 2002 and 2008 NOSB recommendations on producer group certification,⁴⁹ including:

- Establishing eligibility criteria for operations to qualify as producer group operations
- Clarifying the function and responsibilities of Internal Control Systems (ICS)
- Clarifying inspection requirements for producer group operations

Additionally, this rule builds upon the NOSB recommendations with additional detail based on public comment and NOP's programmatic experience auditing certifying agents and witnessing producer group inspections. These additions include requirements for more specific ICS requirements, more specific member and group information in OSPs, and an improved inspection sampling rate.

This rule strengthens the oversight of organic supply chains by enabling certifying agents to more readily assess a producer group operation's compliance with the USDA organic regulations. Certifying agents and operations that are certified as part of a

producer group may be affected by these requirements. Readers should carefully review the regulatory text and policy discussion to determine if the requirements apply to them.

Background

Producer group operations export important organic agricultural products to the United States, such as coffee, cocoa, bananas, tea, and spices.⁴⁴ Globally, there are about 2.6 million organic producers organized across 5,900 producer group operations in 58 countries (mainly in Africa, Asia, and Latin America), managing a total area of about 4.5 million hectares (11 million acres) of certified organic land.⁴⁵

Producer group operations present unique certification challenges. Producer groups may have thousands of members spread across a large area. The collection, handling, and processing of crops may be centralized, and these groups may also rely on centralized input procurement, training, and marketing to sell their product. These centralized practices can introduce risks to traceability and organic integrity due to producer group operations' unique structure, size, and reliance upon internal quality control systems (the ICS) as the first layer of oversight. Through certification audits and field visits, USDA has witnessed many of the common problems created by the lack of a codified producer group standard.

The most common, and difficult to address, challenge is lack of a well-functioning ICS. The ICS is the first line of oversight and enforcement and is responsible for critical functions such as education and inspection of members, and ensuring adherence to the organic regulations. A poorly functioning ICS often leads to poorly trained members who do not understand basic organic principles, and the ICS's lack of effective oversight means members' mistakes go unreported, resulting in a breakdown of the basic oversight

⁴⁴ Producer groups may also be called "grower groups." The latter term is commonly used when certification of group operations is limited to the production or harvest of crops or wild crops.

⁴⁵ Florentine Meinshausen, Toralf Richter, Johan Blockeel and Beate Huber Project: Consolidation of the Local Organic Certification Bodies – ConsCert (2014-2018) // March 2019
<https://orgprints.org/id/eprint/35159/7/fibl-2019-ics.pdf>

necessary to ensure that products meet the USDA organic standard. As a result, NOP audits have uncovered issues such as application of prohibited synthetic fertilizers and pesticides, mixing of conventional and organic products, decentralized storage that causes mixing and contamination, and poor or nonexistent recordkeeping that makes traceability and verification of integrity difficult. These issues sometimes persist because the current regulations lack ICS responsibilities and NOP therefore has no mechanism or basis for citing noncompliance.

Conflict of interest can also become a challenge if not specifically addressed by the ICS. Often, ICS personnel are relatives or friends of the members and may withhold or obscure evidence of noncompliance or fraud. In other cases, the influence of a buyer or exporter will lead members to compromise organic integrity in order to meet specific quality or volume targets.

In addition to the ICS, the lack of general criteria that producer groups must meet creates challenges for certifying agents. This is most often seen as an absence of critical information about the producer group and its members. Producer groups often do not provide certifying agents with basic information, such as accurate maps, location of plots, acreage, and production practices and inputs. During inspection, certifying agents commonly cannot locate members, plots, boundaries, or central distribution points, making it difficult to complete basic audit techniques such as yield analysis or mass balance.

The unique conditions of producer group production mentioned above, when combined with poor oversight and enforcement mechanisms at the ICS level, create an environment where loss of organic integrity and organic fraud are more likely to occur. The organic regulation currently does not have the specificity to address these unique challenges, making it challenging to both discover and correct issues that are prevalent in producer groups. The provisions in this rule codify specific eligibility criteria, ICS

requirements, and inspection techniques to address these challenges, and the rule will give certifying agents the ability to successfully certify and oversee producer group operations and the products they produce.

The International Federation of Organic Agriculture Movements (IFOAM)⁴⁶ started developing criteria for producer group certification in 1994, and in 2003 published its position on “Small Holder Group Certification for organic production and processing” to support the concept.⁴⁷ The criteria formed the basis for acceptance of producer group certification in the European Union (EU) and the United States. Producer group operation certification is also used by other standards organizations, such as the International Accreditation Forum and Global G.A.P., to provide small-holder farming operations access to markets, expand consumer choices, and ensure the integrity of the supply chain.⁴⁸

Organic certification standards for producer group operations support strong and consistent oversight and enforcement of producer group operations. This final rule addresses 2002 and 2008 NOSB recommendations on producer group certification and adds detail about documentation requirements and inspection methods in response to public comments to the proposed rule.⁴⁹ While there are only a few known producer groups in the U.S. at this time, setting requirements for producer groups may help U.S. producer group members access the organic cost-share program and crop insurance.

⁴⁶ <https://www.ifoam.bio/>

⁴⁷ https://www.ifoam-eu.org/sites/default/files/page/files/small_holder_group_certification_0.pdf

⁴⁸ <https://www.iaf.nu/>; https://www.globalgap.org/uk_en/

⁴⁹ NOSB Recommendation: Criteria for Certification of Grower Groups. October 20, 2002: <https://www.ams.usda.gov/sites/default/files/media/Rec%20Criteria%20for%20Certification%20of%20Grower%20Groups.pdf>

NOSB Recommendation: Certifying Operations with Multiple Production Units, Sites, and Facilities under the National Organic Program. November 19, 2008: <https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Certifying%20Operations%20with%20Multiple%20Sites.pdf>

These regulations support the legitimate status of U.S. producer group members as part of an organic operation.

Qualifying as a producer group operation

Certifying agents must assess whether operations that apply for or maintain producer group certification meet the characteristics in the definitions for *producer group member*, *producer group operation*, and *producer group production unit* and the qualifications for certification as producer group operations in 205.400(g). Operations that do not meet all criteria must not be certified as a producer group operation.

The smallest unit of a producer group operation is a *producer group member*. A producer group member is an individual engaged in the activity of producing or harvesting agricultural products as a member of a producer group operation. The practices of each producer group member must align with the organic system plan (OSP) of the producer group. Each member must use practices that comply with the requirements for producers and handlers in the USDA organic regulations. Some requirements may be met collectively by the producer group operation, such as submitting an organic system plan.

Producer group members are organized into production units. A *producer group production unit* is a defined subgroup of producer group members in geographic proximity within a single producer group operation that use shared practices and resources to produce similar agricultural products. Each producer group operation determines the producer group production units in its operation and must identify these in the organic system plan per § 205.201(c)(4).

A *producer group operation* is a producer, organized as a person, consisting of producer group members and production units in geographic proximity governed by an internal control system under one organic system plan and certification. A producer group operation must define its geographic proximity criteria for its producer members

and production units § 205.201(c)(4). The site-specific conditions of an operation, such as infrastructure, topography, common soil, water source, and products produced will affect “geographic proximity.” Therefore, AMS is requiring that certifying agents document and adopt their own criteria or guidelines for internal consistency when establishing acceptable distances or evaluating the geographic reach of a producer group operation.

Producer group operations may be certified for crops, wild crops, livestock, and handling. The requirements for production and handling operations in the USDA organic regulations also apply to producer group operations.

Structure and organization of producer group operations

A producer group operation must be organized as a person (§ 205.400(g)(1)). Organization as a person provides a path to certification because OFPA and the USDA organic regulations apply to a person as the basic regulatory unit. The definition for *person* at 7 U.S.C. 6502(16) and § 205.2 includes groups (e.g., “...association, cooperative, or other entity”). Therefore, certification may be granted to the producer group operation, rather than individual producer group members.

A producer group operation must use centralized processing, distribution, and marketing facilities and systems (§ 205.400(g)(2)). A group may have several facilities for aggregating the products of producer group members and production units and moving into commerce.

An internal control system (ICS) is a defining component of producer group operations and is critical for management of the operation. The ICS is an additional tier of oversight and enforcement between the producer group members and the certifying agent. All producer group operations must have an ICS that implements the practices and procedures described in the organic system plan (§ 205.400(g)(4)). Further ICS requirements are discussed in the following section.

All products sold, labeled, or represented as organic by a producer group operation must be produced or harvested only by producer group members on land and using facilities that are included in the producer group operation's certification (§ 205.400(g)(5)). This means that, for example, a producer group member from one operation (A) must not use a handling facility owned by another producer group operation (B) unless the facility is included in the organic system plan and the producer group operation's (A) certification. A producer group operation must not buy products from non-member producers and sell, label, or represent them as organic using the producer group certification. Likewise, producer group members must not sell, label, or represent their products as organic outside of the producer group operation unless they are individually certified (§ 205.400(g)(6)). This accommodates producer group operations with members of varying production levels where some members have the capacity and need for marketing channels in addition to the producer group operation. When this occurs, clear and careful recordkeeping is essential for successful mass-balance audits.

Producer group operations must provide a comprehensive inventory of the producer group operation and its capacity to the certifying agent. Specifically, the operation must provide the name and location of each producer group member and producer group production unit(s), and identify all products produced, estimated yield(s), and the sizes of the production and harvesting areas (§ 205.400(g)(7)). Producer group operations must provide this information to the certifying agent at least annually and should inform the certifying agent more frequently of changes that may affect its compliance with OFPA or the USDA organic regulations, e.g., additional crops produced, inclusion of new land area and producer group members.

Producer group operations must also show evidence of compliance with the USDA organic regulations through internal inspections and reporting sanctions imposed on

producer group members. It is not feasible for certifying agents to inspect each producer member annually, due to the number of members in any one producer group operation. However, the producer member must attend the internal inspection to provide complete information about their production activities (§ 205.400(g)(8)). Internal inspections must include mass-balance audits and reconciliation of each producer group member's and each producer group production unit's yield and group sales. Records are critical to demonstrate compliance and producer group operations must maintain a recordkeeping system so that products are traceable from producer group members' individual production parcel to aggregation and handling at the production unit and through sale or transport when the products leave the custody and ownership of the producer group operation (§ 205.400(g)(9)).

Internal control systems

Pursuant to the 2002 NOSB recommendation “Criteria for Certification of Grower Groups”⁵⁰ and an August 2020 IFOAM position paper,⁵¹ all producer group operations must have an *internal control system* (ICS). The *internal control system* is an internal quality management system that establishes and governs the review, monitoring, training, and inspection of the producer group operation, and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations. The ICS consists of both the personnel and the procedures that form a producer group's internal governance, verification, and enforcement system. The ICS is responsible for the overall governance and compliance of the producer group

⁵⁰ NOSB Formal Recommendation, Criteria for Certification of Grower Groups, October 20, 2002:
<https://www.ams.usda.gov/sites/default/files/media/Rec%20Criteria%20for%20Certification%20of%20Grower%20Groups.pdf>

⁵¹ “Internal Control Systems (ICS) for Group Certification,” IFOAM Organics International, August 2020,
<https://www.ifoam.bio/our-work/how/standards-certification/internal-control>.

operation and verifies each member's adherence to the organic system plan and USDA organic regulations.

ICS functions

A producer group operation must have an OSP that meets the requirements for all operations in § 205.201(a) and additionally must describe its ICS procedures and practices. Section 205.201(c) describes the OSP requirements that are specific to producer group operations. The OSP for a producer group operation needs to include a description of the ICS and how it verifies the operation's compliance with the USDA organic regulations. This includes defining the organizational structure, roles, qualifications, and responsibilities of all ICS personnel (§ 205.201(c)(1)). Personnel qualifications could include, for example, knowledge of local production practices, organic production and handling practices, ICS procedures, USDA organic regulations, and fluency in the language(s) of the producer group operation.

The ICS must also describe and prevent conflicts of interest between ICS personnel and the producer group operation that it oversees (§ 205.201(c)(3)). The USDA organic regulations identify conflict of interest scenarios for certifying agent and operations (§ 205.501(a)(11)). The ICS personnel-producer member relationship is different than the certifying agent-certified operation relationship so these criteria are not wholly applicable to producer group operations. For example, certifying agents are not permitted to consult with operations to overcome obstacles to certification. However, ICS personnel are required to provide training, education, and resources to assist producer members with awareness of, and compliance with, organic requirements. A generally accepted criteria for conflict of interest is whether an oversight entity, e.g., the ICS, has a financial interest in the regulated party or likely bias based on familial relations. For example, internal inspectors should not inspect family members or production units where the inspector is a member.

The oversight function of the ICS places its personnel at a higher risk for retribution from producer group operations. To support the integrity of ICS oversight, the ICS must also describe how it will protect ICS personnel from retaliation for carrying out their responsibilities, and, in particular, finding and reporting noncompliances (§ 205.201(c)(3)). This could include obtaining a written guarantee from the producer group operation that ICS personnel will not be subject to retribution and requiring ICS personnel to disclose any conflicts of interest prior to internal inspections or review.

The ICS must document and apply procedures for adding new members to a producer group operation (§ 205.201(c)(5)). These procedures must cover how each new member will be inspected by the ICS and evaluated to determine whether they can fully comply with the organic production and handling requirements before they are added as a producer member.

Producer group members use common practices to produce, harvest, and handle their collective products and common inputs. Shared farming or harvesting practices could include fertility and pest management, procurement of inputs (including seeds or soil amendments), and shared resources could include post-harvest handling facilities. The ICS must describe how shared resources, including production practices and inputs, are procured and provided to all producer group members and personnel (§ 205.201(c)(7)). Shared practices and inputs are critical to fostering compliance among many individual farmers and documenting these practices is an important indicator of compliance for the entire operation. Training, education, and technical assistance are critical practices to support consistent and compliant practices among producer members and the description of the ICS must explain how these resources are provided (§ 205.201(c)(8)).

Internal oversight

The ICS is the first line of oversight of a producer group operation and is responsible for assessing the compliance of producer group members. The USDA organic

regulations include several requirements to ensure that the ICS provides competent and thorough oversight. More generally, the ICS must have documented clear policies and procedures to verify the producer group operation's and producer group members' compliance with the USDA organic regulations (§ 205.201(c)).

The ICS must identify criteria for high-risk producer group members and production units (§ 205.201(c)(6)). Certifying agents must also determine which producer members are high risk. Examples of risk factors that may be used by both the ICS and the certifying agent are listed below in the discussion of on-site inspection by the certifying agent.

Clear and comprehensive records are a critical component of an ICS. They help certifying agents understand how the operation is implementing its organic system plan and complying with the USDA organic regulations. The organic system plan must describe the system of records maintained by the ICS (§ 205.201(c)(9)). The system of records must show how records will support and be used for mass-balance calculations and traceability throughout the operation. For full traceability, records would need to cover the purchase, acquisition, or production of products for each producer member through sale or transport.

The description of the ICS must explain internal monitoring, surveillance, sanctions, inspection, and auditing methods used to assess compliance of all producer group members (§ 205.201(c)(10)). As a best practice, internal monitoring and surveillance should cover critical organic control points may include, for example, buffer areas, condition of crops and/or wild crops and animals, soil quality indicators, handling practices, input and equipment use and storage areas. A description of sanctions may cover the review of internal inspection results to determine member compliance; and the processes to address noncompliances, impose sanctions, remove noncompliant producer group members and reporting noncompliances to the certifying agent. A description of

the auditing methods could cover mass-balance audits to reconcile the expected and actual yields and sales of producer members, producer group production units, and producer group operations.

On-site inspections by the certifying agent

Certifying agents are the second tier of oversight for producer group operations. Certifying agents, in addition to verifying that producer group operations are fully compliant with the eligibility, certification and ICS requirements, must follow specific requirements for on-site inspections of producer group operations. Initial and annual on-site inspections of producer group operations must comply with the general requirements for inspections in § 205.403. During annual on-site inspections of producer group operations, certifying agents are required to evaluate the ICS, review internal inspections conducted by the ICS of individual members, and observe ICS personnel conducting internal inspections (§ 205.403(a)(2)(i)-(ii)). At least one producer group member from each producer group production unit must be inspected, and each handling facility, including all collection sites, must be inspected (§ 205.403(a)(2)(iii)-(iv)). Collection sites, where the harvest from multiple producer group members is stored before transport, are handling facilities, and are inspected by certifying agents. USDA organic regulations do not set a minimum number or percentage of witness inspections that a certifying agent must conduct at each producer group operation inspection. Witness inspections are a key component of assessing the ICS and certifying agents will need to ensure that the number of witness inspections at a given operation is sufficient to evaluate ICS rigor.

During on-site inspections, certifying agents must inspect at least 1.4 times the square root or 2% of the total number of producer group members, whichever is higher (§

205.403(a)(2)(iii)).⁵² The square root sampling rate aligns with industry practice. Two sampling rates are provided because the power of the square root sampling power begins to decline when operations exceed 5,000 members so that a smaller proportion of members are inspected relative to the total number of members. The addition of the 2% rate more evenly distributes the number of external inspections across producer groups regardless of the number of members as shown in Table 1. For each producer group operation, certifying agents need to calculate the number of members to inspect using the square root method and the 2% rate and use the higher number.

Table 1

Certifying Agent ICS Inspection Sampling Rates			
Producer Group Members (N)	Square Root Method	Flat 2%	Final Rule
N	$1.4 * \sqrt{N}$	2%	Greater of $1.4 * \sqrt{N}$ or 2%
50	10	1	10
100	14	2	14
250	23	5	23
500	32	10	32
1000	45	20	45
5000	99	100	100
7500	122	150	150
10000	140	200	200

The number of producer group members inspected by the certifying agent must include all high-risk members (§ 205.403(a)(2)(iii)). Certifying agents must inspect at least one producer group member in each production unit (as defined in § 205.2) to ensure all producer group production units are inspected, as well as each handling facility. As a best practice, AMS recommends that certifying agents also select members from across the risk spectrum—including lower-risk members—so that the same

⁵² The square root sampling scheme was developed in the 1920s as a sampling scheme for agricultural regulatory inspectors. The formula used was the square root (Sqrt) of the lot size (N) + 1. Blanck, F.C. (1927). “Report of the Committee on Sampling,” J. Assoc. Official Agricultural Chemists, 10, 92–98.

producer members are not inspected year after year. This may require a sample size larger than the minimum required (i.e., more than 1.4 times the square root or more than 2% of the number of producer group members). All numbers must be rounded up to the next whole number (e.g., using square root method, 50 members = 10 inspections, 100 members = 14 inspections, 500 members = 31 inspections, and 1,000 members = 44 inspections). The certifying agent has the discretion to inspect more producer group members than the minimum indicated by the calculation.

Risk-based inspections rely upon certifying agents having policies and procedures to determine the risk factors associated with producer group operations. While the ICS determines which producer members and production units are high-risk according to their criteria, the certifying agent needs to independently determine which members are high-risk (§ 205.403(a)(2)(iii)). The certifying agent should apply the risk assessment procedures to determine and instruct the inspector on which producer group members to inspect during the annual inspection. After all risk-based and other inspection selection criteria are satisfied, certifying agents should randomly select the remaining member inspections so that different lower-risk producer group members are inspected each year.

Risk factors may include, but are not limited to, producer group administrative capacity, organization complexity, and variations in members and production units (such as product quantity and value, member size, number of products), rate of growth, and compliance and enforcement history. For example, a producer group member selling products outside of the producer group or a producer group member that is considerably larger than the other producer group members in a production unit represent compliance risks to the overall producer group operation. When assessing the risks of the producer group operation to determine which producer group members to inspect, examples of risk factors that the certifying agent may consider include, but are not limited to:

- Noncompliance history of overall producer group and of individual members;

- The criteria used to designate a collection of producer group members as a single producer group production unit;
- High-risk members identified in the ICS and producer groups member with noncompliances;
- Application of prohibited materials adjacent to member fields;
- Split or parallel operations (i.e., operations that are also producing nonorganic agricultural products);
- Producer group members with incomes greater than \$5,000 USD per year;
- The procurement, availability, and distribution of inputs and resources to members;
- The prevalence of nonorganic production of similar products and crops in the region;
- Post-harvest handling practices designed to prevent commingling and contact with prohibited substances;
- New producer group members;
- Size of producer group member's production or gathering areas; and
- Significant expansion of a producer group member's production area.

As a best practice, the inspection of the ICS should also include: document review; auditing of production and sales/distribution records; reconciliation of product inventory; review of procurement and distribution of inputs; review of the inspections conducted by the ICS; review of ICS personnel qualifications and training; witness audits to observe ICS inspectors; review of noncompliance actions for producer group members; examination of organic control points and high-risk areas; interviews with managers responsible for the OSP, governance of the ICS, and producer group members and individuals overseen by the ICS; and review of training provided to ICS staff and producer group members.

Summary of changes to final rule

AMS made several changes to the proposed regulatory text when writing this final rule. Changes to the final rule are discussed below and are followed by responses to specific themes from public comment.

- AMS revised the definitions of *producer group member*, *producer group operation*, *producer group production unit* and *internal control system* to allow livestock production and to clarify that the operation is regulated as a person. Use of the term “individual” in *producer group member* and “person” in *producer group operation* more clearly indicates that the operation is the legal regulated entity, which is consistent with current regulation and ties to the existing defined term *person* (see § 205.2).
- AMS replaced “crop/wild-crop” with “agricultural product” throughout so that livestock and livestock products are not excluded from producer group operation production. Public commenters argued that a prohibition on livestock in producer group certification may disproportionately affect poor and small-scale farmers that depend on producer groups to access the organic market. Livestock production in producer group certification is consistent with EU organic standards, IFOAM, the 2008 NOSB recommendation, and current practice in the organic industry. Allowing livestock production avoids market disruption and negative impact to operations that depend on producer group certification for market access.
- AMS added more specificity to the description of the ICS in the organic system plan, including: describing qualifications of ICS personnel; procedures for approving new members; policies to protect ICS personnel from retribution; description of technical assistance to members; and a system of records that covers each member and support mass-balance audits and traceability. Public

comments stressed the importance of the ICS and suggested modifications to strengthen the ICS's ability to enforce the organic regulations and maintain organic integrity. AMS agrees with public comments and has revised ICS requirements to be more specific because this is necessary to bolster the oversight and enforcement of producer groups.

- AMS clarified that producer group operations must only sell products from the land and facilities included in the certification. The proposed text only specified “from grower group members.” Additionally, requiring that producer groups only sell products produced using land and facilities within the certified operation improves oversight because these facilities and land are routinely inspected by the ICS and the certifying agent.
- AMS added a requirement that producer group operations must maintain an ICS as described in the organic system plan. Although it was implied, proposed § 205.400(g) did not include an explicit requirement to maintain an ICS and did not reference the ICS requirements (§ 205.201(c)). Adding this explicit requirement makes an ICS a clear condition of certification that must be included as part of an organic system plan.
- AMS clarified that producer group members must be present during internal inspections. Having producer group members present during onsite internal inspections is necessary so that ICS personnel can interact with and ask questions of the members to ensure a full understanding of the activities on the members' production sites.
- AMS removed a redundant requirement from § 205.400(g) that the producer group operation must document and report the use of sanctions; the description and implementation of a system of sanctions is covered in §§ 205.201(c)(10) and 205.400(g)(4) and (10).

- AMS adjusted the sampling rates certifying agents must use when inspecting producer groups to 1.4 times the square root or 2% of the total number of producer group members, whichever is higher. The proposed inspection rate of 1.4 times the number of members is a digressive rate, which samples a smaller percentage of members as a group grows larger. Combining this with a linear 2% sampling rate ensures that larger producer groups (those with more than 5,000 members) are inspected at a similar rate as smaller groups.
- AMS revised § 205.403(a)(2)(iii) to clarify that a certifying agent must inspect all producer group members determined to be high-risk by the certifying agent. The proposed rule had stated that high-risk members should be chosen based on the ICS's risk criteria. This change improves oversight by ensuring that a certifying agent conducts independent risk assessments based on their own risk criteria, rather than relying only on the ICS's assessment.

Summary of public comments

The majority of public comments received supported AMS's codification of producer group standards in the USDA organic regulations. Many comments provided suggestions and recommendations to the proposed policy.

Many comments strongly opposed the proposed prohibition of livestock production within producer groups, requesting that AMS revise the standard to allow "scope neutrality" and the production of livestock and livestock products. Several commenters stated that many certified producer groups already produce livestock and livestock products, and that prohibiting livestock would negatively impact these operations.

Several comments suggested AMS add more specificity to the proposed ICS requirements to ensure the ICS can manage the unique challenges of producer groups. Commenters requested more detail about conflict of interest, training, risk assessment, inspections, recordkeeping, personnel qualifications, protections for farmers, and

evaluation of the ICS by the certifying agent. Commenters pointed to specific details found in the preamble describing organic system plans and the internal control system and requested these be added to the final rule to support clarity and consistency.

The proposed rule asked if producer group risk should be managed by placing limits on scale (e.g., number of members, size of individual members, geographic distribution of members). Most commenters agreed that the risks of uncontrolled size or scale should be addressed but felt prescriptive limits may arbitrarily exclude members, disrupt well-functioning groups, restrict economic opportunity, or force producers to revert to conventional methods. The majority of commenters advocated for “scale neutrality” and requested NOP develop alternate strategies to manage the risks of large producer group operations.

Several comments requested that AMS require the use of risk criteria and assessment to control issues of scale. Others recommended that AMS develop a separate scope of accreditation specifically for producer groups, arguing that certification of these operations requires specialized skill and oversight. A few comments noted the difficulty of identifying producer groups in the Organic Integrity Database, and asked for identification to be mandatory. Some comments noted differences between the proposed policy and other international standards, and asked AMS to align its producer group standards with EU and IFOAM. Finally, a few comments expressed concern that the producer group standard may be used by large livestock or poultry cooperatives in the United States, which they argue is against the intent of the standard to support opportunity and growth for very small organic farmers.

Responses to public comments

(Comment) Some commenters recommended specific limits on parcel size and number of members in a producer group operation because a lack of controls on scale could lead to inadequate and inconsistent enforcement. Commenters mentioned that an ICS could

be reluctant to enforce against a large producer member without which the producer group could fail.

(Response) AMS is not setting size limitations, in terms of land area or number of members, on producer group operations. The ICS requirements support effective oversight of producer group operations regardless of their size.

(Comment) Comments opposed the proposed prohibition of livestock producer group operations. Commenters argued that this may disproportionately affect poor and small-scale farmers that depend on producer groups to access the organic market. Some comments mentioned that livestock producer group operations are already certified for beef and honey production.

(Response) AMS revised the proposed rule to allow the certification of livestock production as producer group operations. This allowance aligns with the EU organic standards for producer group operations and the 2008 NOSB recommendation, which did not restrict producer group certification to crop and wild crop operations. Livestock producer group operations may be more complex and higher risk than crop and wild crop producer group operations. In practice, this will require careful oversight of the ICS and qualifications of ICS inspectors and personnel. Further, some types of livestock production may be unsuitable for group certification (e.g., intensive livestock farming, variability between producer members) because it is more difficult for them to meet the requirements for certification as a producer group operation.

(Comment) Comments requested a separate scope of accreditation for producer group certification to ensure that certifying agents are sufficiently qualified to certify producer groups.

(Response) Establishing a separate scope of accreditation would require more input and assessment of impacts, as this was not included in the proposed rule. This type of certification is complex and presents higher risks for organic integrity. AMS will assess

certifying agents' oversight of and qualifications for producer group certification through rigorous audits.

(Comment) Comments suggested that the ICS should describe the qualifications of all ICS personnel and the procedure to ensure the availability of a sufficient number of qualified personnel. Comments specified that the ICS should describe how ICS personnel are familiar with the local production practices, general organic production and handling practices, the USDA organic regulations, ICS procedures and regulations, and be fluent in the language(s) of the producer group members and the ICS.

(Response) The description of the ICS must describe the qualifications and responsibilities of ICS personnel. AMS has identified examples of the knowledge qualifications for ICS personnel, but is not adding these as required to give flexibility to certifying agents to determine the suitable qualifications on specific operations.

(Comment) Comments asserted that producer group operations must ensure that all group members understand and can comply with the USDA organic regulations. Commenters urged that the ICS should describe how the training, education, and technical assistance that is provided to producer group members and ICS personnel ensures their understanding of and compliance with internal control system's policies, the organic system plan, and the USDA organic regulations.

(Response) Producer group operation compliance requires that each member understand the required and prohibited practices for organic production and handling. AMS has added a requirement for the ICS to include training, education, and technical assistance to producer members (205.201(c)(8)). Given that producer group operations are located in areas with varying language and literacy proficiency, it is the responsibility of the operation to effectively communicate this information to all members on an ongoing basis.

(Comment) Comments stated that the ICS should explain how it manages conflicts of interest by addressing or prohibiting internal inspectors from inspecting or acting as buying officers for their own relatives. Comments also requested guidance around conflict-of-interest scenarios and that internal inspectors are not restricted from providing training, education, or technical assistance to producer group members.

(Response) The description of the ICS must explain how it will prevent potential conflicts of interest. The development of guidance on specific examples of conflict of interest needs further public input and discussion and that level of detail was not included in the scope of this rule. Certifying agents will review the ICS to determine if known potential conflicts of interest are identified and prevented. AMS agrees that internal inspectors inspecting or procuring products from their relatives would be potential conflicts of interest because the relationship may compromise the inspector's objectivity in assessing compliance.

(Comment) Comments stressed that group members need to be present during their internal inspection and that more guidance is needed to ensure the ICS is addressing noncompliances and reporting major noncompliances to the certifying agent.

(Response) AMS has added the requirement for producer members to be present at the inspection of their production site(s). Maintaining an organized, transparent, and equitable system of sanctions is critical for producer group certification. The ICS must have procedures for implementing a system of sanctions, and the producer group operation must report sanctions for noncompliant members to the certifying agent. The requirements for recordkeeping that covers internal inspection reports, sanctions, and corrective actions plus the external inspection requirements will help certifying agents to assess whether the ICS is reporting noncompliances and sanctions to the certifying agent.

(Comment) Comments supported that the ICS describe the recordkeeping system that must cover signed member agreements, internal inspection reports, documents related to

internal sanctions and corrections, and formal agreements for each producer group member that commits them to complying with ICS, OSP, and USDA organic regulations, along with all training records for members and personnel. The ICS procedures should state how lists of individual members, locations, products, acreage, copies of inspection reports, sanctions, and corrections are stored and made available during inspection by the certifying agent.

(Response) The USDA organic regulations require a description and implementation of the recordkeeping system. The critical objective of recordkeeping is to support traceability of production, inputs, and transactions throughout the producer group operation. Information about sanctions and internal inspection reports are required by separate provisions.

(Comment) Comments requested clarification about what types of noncompliances (i.e., major vs minor) must be reported to the certifying agent.

(Response) The requirement to report noncompliances to the certifying agent enables the certifying agent to assess ICS oversight. It also leaves flexibility for the ICS to describe different timing and reporting methods for noncompliances of varying scope and severity. Noncompliances that may result in removal of the member(s) from the producer group, for example, application of prohibited substances, warrant timely notification to the certifying agent. In contrast, maintaining records of correctable noncompliances for the certifying agent to review during external inspections would be acceptable.

(Comment) Comments stated that the use of 1.4 times the square root of the number of members is not adequate for external inspections. They explained that this inspection rate is either too low for a producer group with more than 5,000 members, resulting in potentially inadequate oversight of very large groups, or the inspection rate is too high and burdensome for small producers, resulting in pressure to grow larger to reduce certification costs. Comments suggested other rates including a flat percentage rate of 2-

3%, a combination of square root and flat rate methods, or a minimum of 10% of producer group members.

(Response) The external inspection sampling rate should be equally stringent for producer member operations regardless of size. The USDA organic regulations specify that certifying agents must use the higher result of 2 sampling rates to set the minimum number of producer members that need to be inspected. Setting 2 rates is necessary because the square root sampling power begins to decline when producer groups are larger than 5,000 members. The use of 1.4 times the square root or 2% of the total number of producer members is a minimum and does not prevent certifying agents from using sampling sizes that exceed the results of those rates. Higher levels of inspection rates may be warranted when necessary if a producer group operation has a history of inadequate internal controls and poorly trained personnel with ineffective policies, procedures, or sanctions, and is failing to enforce against noncompliant members, failing to inspect all members, or is not completing mass-balance audits.

O. Calculating the Percentage of Organically Produced Ingredients.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.302	Calculating the percentage of organically produced ingredients. Paragraphs (a)(1), (2), and (3).

This rulemaking revises § 205.302(a) to clarify that the percentage of organic ingredients in multi-ingredient products should be calculated by dividing the weight or volume of the organic ingredients at formulation by the total weight or volume of the product at formulation, with water and salt added as ingredients at formulation excluded from the calculation.

This policy may affect certified operations, noncertified operations that process products containing organic ingredients, applicants for organic certification, and

certifying agents. The reader should carefully examine the regulatory text and discussion below.

Background

Section 205.301 of the organic regulations classify products containing organic ingredients into several categories based on percent composition—e.g., “100 percent organic,” “organic,” “made with organic (specified ingredients or food group(s)).” Clear and easily understood instructions for calculating product composition are needed to ensure consistent classification by the organic industry.

Previous policy had sometimes caused inconsistent implementation because it required calculation based on “total weight of the finished product.” It was unclear if this meant products before or after processing. Because processing (e.g., cooking, baking, dehydrating, freeze drying) often causes water loss from ingredients, using the total weight of the product after processing sometimes resulted in inflated percent organic content calculations. This rulemaking clarifies that organic content must be calculated from the weight of ingredients at formulation (i.e., *before* processing such as baking or cooking). This will ensure correct calculation of organic content so that labels on multi-ingredient organic products are accurately listed. This requirement also addresses an existing point of confusion and will increase the consistency of organic labeling claims in processed organic products. This policy is consistent with both an April 2013 NOSB recommendation⁵³ and NOP 5037 Draft Guidance published by AMS in December 2016.⁵⁴

⁵³ NOSB Recommendation, Calculating Percentage Organic in Multi-Ingredient Products, April 11, 2013: <https://www.ams.usda.gov/sites/default/files/media/NOP%20CACC%20Final%20Rec%20Calculating%20Percentage.pdf>

⁵⁴ The draft guidance and comments can be viewed at <https://www.regulations.gov/document?D=AMS-NOP-16-0085-0001> and in the NOP Program Handbook: <https://www.ams.usda.gov/sites/default/files/media/NOP5037DraftGuidancePercentCalculations.pdf>

Calculating percentage of organic ingredients

To calculate the percentage of organic ingredients in a multi-ingredient product, divide the weight or volume of the organic ingredients at formulation by the total weight or volume of the product at formulation. If water and salt are added as ingredients, these must be excluded from the calculation. If a multi-ingredient product contains only liquids, volume must be used for calculation. If a product contains both solid and liquid ingredients, weight must be used for calculation. Please see Table 2, below, for an example of how to calculate the percentage organic content of a multi-ingredient product.

Liquid ingredients being reconstituted from concentrates should be calculated based on single-strength concentrations. The term “single-strength” is defined by the Food and Drug Administration (21 CFR 101) as equivalent to the Brix value of 100 percent juice. Brix is a measurement referring to the percent, by mass, of soluble solids (generally sugar) in a solution. Brix is a useful reference in identifying single-strength identities of juices (see 21 CFR 101.30(h)(1)) as the mass of sugar and other soluble solids is not affected by the concentration process (i.e., the same mass of sugar will be present in 1 liter of apple juice measured at 11.5 Brix, as is present in 0.5 liters of concentrated apple juice measured at 23 Brix). Reconstitution is taking a concentrated juice product and adding water to dilute the concentrated juice back to single-strength values. Using the previous example, if a producer starts with 0.5 liters of concentrated apple juice, they could add water to increase the total volume to 1 liter, bringing the juice back to the original Brix value of 11.5. Allowing for reconstituting concentrated juice gives producers flexibility in shipping, storage, and use of juice products in organic production.

For products that have ingredients composed of multiple ingredients (also referred to as “multi-ingredient ingredients”), the exact organic content should be obtained of that multi-ingredient ingredient when calculating the total organic content of the final organic product. In this case, the calculation should identify the organic and nonorganic parts of

the multi-ingredient ingredient and supporting documentation should be available for the certifying agent to review. Alternatively, these ingredients should be calculated as contributing either 95% organic content or 70% organic content depending on how the product is classified (i.e., either “organic” or “made with organic (specified ingredients or food groups)” respectively).

Table 2. Calculating Percent Organic of a Soy Beverage

Ingredient	Weight of ingredient at formulation	% organic content of ingredient	% in formulation	Actual organic %
Organic Soy Base	1,100 lbs.	100%	16.42%	16.4200%
Organic Cane Sugar	5,288 lbs.	100%	78.94%	78.9400%
Organic Vanilla Extract	60 lbs.	95%	0.89%	0.8455%
Vitamins	50 lbs.	0%	0.74%	0.0000%
Calcium Phosphate	100 lbs.	0%	1.49%	0.0000%
Carrageenan	100 lbs.	0%	1.49%	0.0000%
Added Water	10,000 lbs.	-	-	-
Added Salt	5 lbs.	-	-	-
Total weight (excluding added salt and water)	6,698 lbs.		Total % Organic	96.2055%

Summary of changes to the final rule

AMS replaced the parenthetical statements “(excluding water and salt)” with the single statement “Water and salt added as ingredients at formulation are excluded from the calculation.” This more clearly states NOP’s intent and will result in more consistent calculation of organic content across the industry.

Summary of public comment

In general, almost all public comments supported AMS’s clarification that percent organic content must be calculated based on weights/volumes at formulation. However, many comments noted that the proposed text could be interpreted to mean that salt and water must be excluded from each ingredient during calculation. Commenters explained

this would be difficult and unnecessary to calculate the amount of water and salt in some ingredients and asked that AMS revise § 205.302(a) to state that only water and salt added as ingredients should be excluded from calculation. However, several comments also asked AMS to clarify that water and salt added to individual ingredients (e.g., broth or tea) should be excluded from calculation.

Responses to public comment

(Comment) Many comments noted that the proposed text could be interpreted to mean that salt and water must be excluded from individual ingredients during calculation.

Commenters explained this would be difficult and unnecessary to calculate the amount of water and salt in some ingredients, and asked that AMS revise § 205.302(a) to state that only water and salt added as ingredients should be excluded from calculation.

(Response) AMS has replaced the parenthetical statements “(excluding water and salt)” with the single statement “Water and salt added as ingredients at formulation are excluded from the calculation.” This clearly states that only water and salt added as ingredients are excluded from calculation.

(Comment) Several comments asked NOP to clarify how to calculate percentage organic content when ingredients are composed of more than one ingredient (a “multi-ingredient ingredient”).

(Response) The exact organic content of a multi-ingredient ingredient should be used when calculating the total organic content of the final organic product.

P. Supply Chain Traceability and Organic Fraud Prevention.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.2	Terms defined. Definitions for <i>Organic fraud</i> and <i>Supply chain traceability</i> .
205.103	Recordkeeping by certified operations. Paragraphs (b)(2), and (3).

205.201	Organic production and handling system plan. Paragraph (a)(3).
205.501	General requirements for accreditation. Paragraphs (a)(10), (13), and (21).
205.504	Evidence of expertise and ability. Paragraphs (b)(4) and (7).

Traceability and fraud prevention are essential in complex organic supply chains. Because protecting and verifying organic integrity is a responsibility shared by many participants in the organic industry, this rulemaking requires certified operations and certifying agents to incorporate supply chain traceability and organic fraud prevention into their practices. These actions will strengthen organic integrity and reinforce trust in the USDA organic label.

Certified organic operations must:

- Maintain records of their activities that span the time of purchase or acquisition, through production, to sale or transport;
- Maintain records that trace back to the last certified operations in their supply chain;
- Maintain audit trail documentation to facilitate supply chain traceability, including identification of agricultural products as organic on audit trail documents; and
- Describe in their organic system plan the monitoring practices and procedures used to prevent organic fraud and verify suppliers and organic product status.

Certifying agents must:

- Conduct risk-based supply chain traceability audits of products they certify to verify compliance;
- Maintain procedures for identifying high-risk operations and agricultural products, conducting risk-based supply chain audits, and reporting credible evidence of organic fraud to the USDA; and

- Share information with other certifying agents to conduct investigations, conduct supply chain traceability audits, and verify compliance of organic products.

These requirements may affect certified organic operations, certifying agents, and operations applying for organic certification. Organic stakeholders should carefully examine the regulatory text and policy discussion below.

Background

Because organic products are credence goods, the organic system relies upon on trust between entities in organic supply chains.⁵⁵ Therefore, traceability and verification of organic products are essential to the function of a healthy organic market. This is especially true of modern organic supply chains, which have grown longer and more complex. Organic products and ingredients are often handled by dozens of operations, including uncertified entities, on their way to the consumer. A robust system of traceability and fraud prevention can help reduce the risks of complex supply chains and minimize fraud.

The length and complexity of modern supply chains present many risks to organic integrity. Activities that can compromise organic integrity and void the use of the USDA organic label include physical risks such as contact with substances prohibited in organic production (e.g., pesticides, fumigants, or cleaning agents) and mixing or commingling of organic and nonorganic products. Integrity can also be compromised if a nonorganic product is mistakenly labeled or identified as organic, or if poor recordkeeping cannot demonstrate that a product was produced on a certified farm and handled according to the organic regulations. Additionally, fraud can occur through falsification of records and labeling to claim that a nonorganic product is certified organic. Breach of integrity can occur at any point in a supply chain, from production to final sale. In addition, the

⁵⁵ A credence good is something with value or qualities that cannot be easily determined by the consumer before, or even after, purchase.

prevalence in organic supply chains of uncertified operations, who do not have direct USDA or certifying agent oversight, increases the chance that loss of integrity may occur and/or go unreported.

Organic products therefore require additional care to verify organic status and ensure that products bought and sold are genuinely organic and have not been compromised. Because full visibility across an entire supply chain is difficult, this rule focuses on using critical information at control points where risk is highest to verify chain of custody and confirm organic integrity. This is primarily done by building a record of product transaction and movement that demonstrates proper handling and maintenance of integrity. Without a verified transaction record, operations (and by extension, consumers) don't have a full picture of a product's history, and breaches of integrity can go unnoticed, allowing compromised product to continue along a supply chain to the consumer.

The current USDA organic regulations require general recordkeeping and verification of organic integrity, but the requirements are not specific and lack key types of information and practices that are necessary to prove the integrity of products from long, complex supply chains. This lack of recordkeeping information often leads to incomplete audit trails, and operations and certifying agents are often unable to verify product origin or organic integrity. The specific recordkeeping, auditing, and fraud prevention procedures in this rule will augment existing practice to ensure more complete visibility into organic supply chains. This visibility will allow operations and certifying agents to complete more rigorous verification of organic products and identify and stop loss of organic integrity before it moves further into organic supply chains.

All successful systems of traceability include three common elements: (1) traceability within a single operation; (2) traceability one step forward and one step back from an operation in a supply chain; and (3) bidirectional traceability along a supply

chain by a third party. This rulemaking supports traceability by clarifying who is responsible for each element: certified organic operations are responsible for traceability within their operation, back to their suppliers, and forward to their customers; certifying agents are responsible for verifying and tracing products along a supply chain and assessing a certified operation's system of traceability.

Fraud is also a significant risk to organic integrity; this rulemaking therefore focuses effort on its prevention. To clarify what this means, § 205.2 of the organic regulations includes a definition of *organic fraud*: deceptive representation, sale, or labeling of nonorganic products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” This broad definition helps clarify portions of this rulemaking's policy (e.g., §§ 205.201(a)(3) and 205.504(b)(7)), but is not intended to be used as a mechanism or criterion for enforcement.

Certified operations

Recordkeeping

Section 205.103 of the organic regulations describes the recordkeeping responsibilities of certified operations. Records are used by operations, certifying agents, the USDA, and others to verify the compliance of organic operations and products. Clear and auditable records also support traceability. This rulemaking clarifies recordkeeping requirements to support the traceability of organic products both within and between operations.

General recordkeeping requirements

Section 205.103(b)(2) specifies that a certified operation's records must describe all activities and transactions of the operation. This includes physical and financial possession, production, handling, title, and contractual oversight responsibilities of the organic products and ingredients the operation produces or handles. Such records must span the time of purchase or acquisition, through production, to sale or transport. This

requirement supports “internal” traceability, or the ability to track the movement, handling, and organic status of products within a single operation. These records are needed to verify the compliance of an organic operation and its products, and supports on-site inspections by providing information for mass-balance audits and traceability verification by certifying agents (see § 205.403(d)(4)–(5)).

Section 205.103(b)(2) also requires that an operation’s records must be sufficient to trace products back through a supply chain to the last certified operation. Keeping “external” records back to the last certified operation is needed to verify the source of organic products. Note that records must reach back to the last *certified* operation. Operations receiving organic products from uncertified suppliers (e.g., an exempt wholesaler) must keep records demonstrating how the uncertified operation maintained organic product integrity. This may require keeping records from several uncertified operations in sequence; in all cases the records must show an audit trail back to the last certified operation. Operations can demonstrate an audit trail by using various types of documentation that are typically used during sale, purchase, and transfer, such as receipts, invoices, shipping or receiving manifests, shipping logs, bills of lading, or transaction certificates. The organic industry creates and transfers this documentation (almost always electronically) in the usual course of business, and sales contracts often list this documentation as a condition of the sale. Typically, handling entities along a supply chain (such as a transporter, broker, or storage facility) will send electronic documentation directly to the buyer either before or at receipt of a product. A buyer may also obtain additional documents or records directly from the certified operation that sold the product.

Maintaining records back to the last certified operation will support supplier verification and fraud prevention plans (§ 205.201(a)(3)). Such records will also ensure certifying agents have the information they need to verify the compliance of products

during on-site inspections (§ 205.403(d)(5)) and during supply chain traceability audits (§ 205.501(a)(21)).

Section 205.103(b)(2) describes a certified operation's minimum recordkeeping requirements. Certified operations may need to keep additional records beyond the scope of § 205.103(b)(2) to comply with other portions of the organic regulations and the Act. For example, to comply with § 205.236, Origin of livestock, livestock operations must maintain records demonstrating that animals were organically managed from the last third of gestation, which may include place and date of birth. This may require records that trace purchased animals back to the operation where the animal was born to prove origin and organic management (i.e., the records must trace *beyond* the last certified operation to prove compliance).

Audit trail documentation

Certified operations must keep audit trail documentation for all organic products they produce or handle. Audit trail documents are records used to determine the source, transfer of ownership, and transportation of organic products (see definition of *audit trail* in § 205.2). For the purpose of audit trail documentation, the "source" of organic products is the certified operation that supplied the product to the operation. Examples of audit trail documentation may include but are not limited to receipts, invoices, shipping or receiving manifests, shipping logs, bills of lading, and transaction certificates. Audit trails must document the history of organic products back to the last certified operation (per § 205.103(b)(2)).

Audit trail documentation must identify organic products as "100% organic," "organic," or "made with organic (specified ingredients or food group(s))," as appropriate. Operations may use abbreviations or acronyms to identify products, provided that the abbreviations or acronyms are easily understood. Certified operations should consider describing use of any abbreviations or acronyms in their OSP; this will

facilitate on-site inspections and record audits by certifying agents, and help ensure that records are “readily understood and audited” (§ 205.103(b)(2)).

Explicit identification of products as organic is required for audit trail records (i.e., “transaction” or “external” records). “Internal” records do not need to provide explicit organic identification (e.g., “100 percent organic”). However, all systems of records must be “in sufficient detail as to be readily understood and audited” to meet the requirements of § 205.103(b)(2). This means that operations must be able to identify products they produce or handle as organic, even if records do not explicitly state “organic.” For example, an operation may use an inventory management system that uses lot codes, batch numbers, or other designation system that indicates organic status. Such designation systems must be clear and auditable to facilitate on-site inspection and verification of compliance.

Audit trail documentation that clearly identifies organic products will support an operation’s verification of suppliers and implementation of fraud prevention plans. They will also allow certifying agents to verify compliance of suppliers and products during on-site inspections (§ 205.403(d)(5)) and supply chain traceability audits (§ 205.501(a)(21)).

Fraud prevention plans

Section 205.201(a)(3) requires all certified operations to maintain and implement practices to verify the organic status of suppliers and products in their supply chain and to prevent organic fraud. Often called “fraud prevention plans,” these procedures and practices support early detection, prevention, and mitigation of fraud, and strengthen integrity across organic supply chains.

A fraud prevention plan must be included in an operation’s OSP. This allows certifying agents to assess the effectiveness of certified operations’ anti-fraud practices and compliance with the organic regulations. A fraud prevention plan must be

appropriate to the activities, scope, and complexity of the operation, and should be sufficient to address the verification and anti-fraud needs of the particular operation. This means not all fraud prevention plans will be alike. For example, a producer who does not handle another operation's organic products may develop a simple fraud prevention that verifies purchased inputs comply with organic regulation. In contrast, a processor that receives many organic ingredients from numerous suppliers should develop a fraud prevention plan that describes practices to detect, prevent, minimize, and mitigate organic fraud risks in lengthy supply chains.

Because fraud prevention plans must verify the organic status of suppliers and organic products, they should include a description of how an operation verifies organic status back to the last certified operation in the supply chain. This supports recordkeeping and audit trail requirements at § 205.103(b)(2) and (3) and allows certifying agents to verify compliance during on-site inspections and supply chain traceability audits.

As a best practice, a robust plan for supply chain oversight and organic fraud prevention may include:

- A map or inventory of the operation's supply chain that identifies suppliers;
- Identification of critical control points in the supply chain where organic fraud or loss of organic status are most likely to occur;
- A vulnerability assessment to identify weaknesses in the operation's practices and supply chain;
- Practices for verifying the organic status of any product they acquire and/or use;
- A process to verify suppliers and minimize supplier risk to organic integrity;
- Mitigation measures to correct vulnerabilities and minimize risks;
- Monitoring practices and verification tools to assess the effectiveness of mitigation measures; and

- A process for reporting suspected organic fraud to certifying agents and the NOP.

Certifying agents

Supply chain traceability audits

Traceability of organic products across multiple operations in a supply chain is an effective strategy to detect fraud, conduct investigations, and verify compliance of products and operations. Therefore, § 205.501(a)(21) of the organic regulations requires certifying agents to conduct risk-based supply chain traceability audits of products and operations they certify.

What is a supply chain traceability audit?

A supply chain traceability audit (SCT audit) is the process of identifying and tracking the movement, sale, custody, handling, and organic status of a product along a supply chain. The objective of a supply chain audit is to verify a product's compliance with the organic regulations. SCT audits can be used to investigate evidence or suspicion of fraud, verify compliance of high-risk products, investigate patterns of activity, trace the source of products contaminated with prohibited substances, surveil high-risk supply chains, or for other compliance-related reasons.

Criteria and procedures for supply chain traceability audits

Certifying agents must maintain criteria and procedures that describe the use of risk-based SCT audits. This must include (1) criteria used to identify high-risk operations and products for SCT audits, and (2) procedures used to conduct SCT audits. SCT audits conducted by the certifying agent must be based on these criteria and procedures. To ensure that AMS is made aware of organic fraud when it is discovered, certifying agents must also maintain procedures to report credible evidence of fraud to the USDA. Copies of these procedures and criteria should be kept by the certifying agent to demonstrate its expertise and ability (§ 205.504(b)(7)); this allows AMS to review and evaluate use of SCT audits during regular accreditation audits.

SCT audits should be initiated by events or criteria chosen and described by the certifying agent. For example, SCT audits may be initiated to investigate evidence or suspicion of fraud, verify compliance of an organic product, investigate patterns of activity, trace the source of positive residue testing, surveil high-risk supply chains or products, or to address any other compliance-related risk, activity, or need identified by the certifying agent.

Use of supply chain traceability audits

The length, extent, and frequency of an SCT audit may vary and should be determined by the objective of the audit (i.e., an SCT audit ends when its objective is achieved). SCT audits may trace back to the origin (production site) of a product, or until a noncompliance is verified or cleared. For example, if a certifying agent's objective is to verify the production origin of an ingredient, the SCT audit should trace the ingredient through the entire supply chain to the farm or ranch where the ingredient was produced. In contrast, if an SCT audit is initiated to determine the source of a positive residue test, the SCT audit may conclude when the source of the contamination is identified (which may only be several "steps" back in the supply chain).

The number, frequency, type, and extent of SCT audits should be appropriate to the number, scope, and complexity of operations the certifying agent certifies.

Information sharing

To facilitate supply chain traceability audits, investigations, and verification of organic status, AMS requires certifying agents share compliance- and enforcement-related information with each other. Per § 205.501(a)(10), certifying agents must maintain strict confidentiality with respect to its clients and not disclose business-related information to third parties that are not involved in the regulation or certification of operations, as required by the OFPA (7 U.S.C. 6515(f)).

Certifying agents must exchange information that is credibly needed to determine an operation's compliance with the USDA organic regulations, including assessment of applications for certification, noncompliance investigations, suspension/revocation of certification, supply chain traceability audits, verification of audit trail documentation, and verification of the organic status of products represented as organic (see § 205.501(a)(10)(ii) and (a)(13)).

Section 205.501(a)(10)(iii) requires that compliance-related proprietary business information exchanged between certifying agents must remain proprietary, and that all certifying agents involved in the exchange must preserve the confidentiality of the information during and after the exchange. Certifying agents must maintain copies of the procedures used to exchange information and maintain confidentiality of information (§ 205.504(b)(4)). These requirements will ensure confidentiality of information during compliance activities that span multiple certified operations and certifying agents, such as supply chain traceability audits and investigations.

Conclusion

The traceability and fraud prevention requirements discussed above are part of a holistic organic control system that enhances the oversight, enforcement, and integrity of organic products. Many other sections of this rule support and facilitate traceability and fraud prevention; stakeholders should read the following sections to better understand how to implement this rule's traceability and fraud prevention requirements:

- Section III. A: Applicability and Exemptions from Certification;
- Section III. B: Imports to the United States;
- Section III. C: Labeling of Nonretail Containers;
- Section III. D: On-Site Inspections;
- Section III. G: Paperwork Submissions to the Administrator; and
- Section III. H: Personnel Training and Qualifications.

Summary of changes to the final rule

AMS made several changes to the proposed regulatory text when writing this final rule. Changes to the proposed rule are discussed below and are followed by responses to specific themes from public comment:

- AMS revised the definition of *organic fraud* to remove “intentional” and “for illicit economic gain.” “Intentional” is not needed because this defined term is not used for enforcement; it is used to help explain the objective of this rulemaking and many of its provisions. AMS removed the phrase “for illicit economic gain” because not all fraud results in or is motivated by economic gain. The final defined term is more flexible than proposed and encompasses a broader range of potential fraud types.
- AMS added the new term *supply chain traceability audit*. A similar definition was used in the preamble of the proposed rule to help stakeholders understand the rule and its objectives. AMS added this new term to more formally clarify its purpose and objective, and to more clearly define the expectations of traceability audits by certifying agents (see § 205.501(a)(21)).
- AMS removed the requirement in § 205.103(b)(2) to identify specific labeling categories (e.g., “100% organic”) in records. Removing this requirement avoids the potential for additional recordkeeping burden that some comments noted the proposed rule could unintentionally create, and gives operations more flexibility in how they keep records.
- AMS specified the scope of recordkeeping in § 205.103(b)(2) to more clearly indicate the types of records that operations should keep, and what timeframe they should span. This presents clear expectations that support traceability and verification of organic products, but also puts clear boundaries on the scope of records to control burden and cost to operations.

- AMS added a requirement to identify organic status (e.g., “100 organic”) in audit trail documentation at § 205.103(b)(3) and added “or similar terms, as applicable.” The proposed rule had included this at (b)(2) as a general requirement for all records; the rulemaking only requires such identification on audit trail documentation (see *audit trail* at § 205.2). This change will avoid the potential for additional recordkeeping burden that some comments noted the proposed rule could unintentionally create, but still ensures that this critical information is available to trace organic products between operations and to verify integrity.
- AMS revised § 205.201(a)(3) to clarify that fraud prevention plans must be appropriate to an operation’s activities, scope, and complexity. This change responds to public comments that were concerned about disproportionate burden (i.e., greater cost) on small operations, especially small producers. This change may allow operations with less complex activities and/or a more limited scope to write and implement simpler fraud prevention plans.
- AMS removed “back to the source” in § 205.501(a)(21) because public comments indicated this phrase was unclear and that the length of supply chain traceability audits varies. The new term *supply chain traceability audit* states the objective of such an audit—to verify an organic product’s compliance—and therefore serves to clarify that the length and extent of supply chain traceability audits will vary depending on the objective and findings of the process.
- In § 205.501(a)(15), AMS added references to § 205.504(b)(7) and § 205.501(a)(13). This more clearly specifies that certifying agents are to use their own criteria for identifying high-risk operations and conducting supply chain traceability audits, and that they are to share information with other certifying agents to conduct audits and verify compliance.

- AMS added the term *supply chain traceability audit* to § 205.504(b)(7) to more clearly state the need for and objectives of the risk criteria and procedures in this paragraph.
- AMS did not change § 205.501(a)(10), § 205.501(a)(13), or § 205.504(b)(4).

Summary of public comment

The majority of public comments supported AMS's proposed revisions to recordkeeping requirements for certified operations. Many comments noted that including a description of full organic status (e.g., "100 percent organic...") on all records may be burdensome and suggested that AMS allow the use of abbreviations, acronyms, or shorthand when identifying organic ingredients. Other comments asked for additional clarity about the definition of *audit trail* and what types of documentation are needed to meet the requirements of § 205.103(b)(3). Finally, a few comments claimed that keeping full organic identification on all records may be burdensome and asked that AMS not finalize this requirement in cases where inventory management systems can indicate organic status via lot codes or batch numbers.

Comments largely supported AMS's proposed use of fraud prevention plans by certified operations. However, many comments requested additional specificity about what should be included in fraud prevention plans. Other comments noted that fraud prevention plans may be difficult for very small businesses to write and implement and recommended AMS develop templates, examples, and generic forms for small operations to use.

AMS received many comments about the proposed definition of *organic fraud*. Some comments requested that AMS remove "illicit" and from the definition, arguing that fraud may not always constitute illegal activity. Others suggested removing "intentional," citing the difficulty of proving intent. Several comments also suggested

AMS harmonize the proposed definition with existing definitions from other organizations such as GFSI, the EU, ISO, and FDA.

Public comment generally supported the proposed use of supply chain traceability audits. Many comments asked AMS to clarify the requirements of and extent of supply chain traceability audits, particularly how far back an audit should trace a product. Others suggested adding a definition of supply chain audit or traceability. Opinions varied widely on the number of supply chain traceability audits to be conducted, with many comments suggesting a minimum percentage of operations or a risk-based selection. Many comments also discussed the administrative impacts of supply chain traceability audits: a few comments claimed some certifying agents may not have the capacity of expertise to conduct audits; others highlighted challenges with information sharing and coordination among certifying agents. A few comments expressed a desire for AMS to coordinate supply chain traceability audits.

Finally, some comments suggested alternatives to AMS's proposed traceability and fraud prevention strategy, including trusted trader programs, increased surveillance by AMS, and exemptions for businesses that already participate in other traceability programs.

Responses to public comment

Definition of organic fraud

(Comment) Comments asked AMS to use “willful” instead of “intentional” in the definition of *organic fraud*.

(Response) The rulemaking does not use “willful” or “intentional” in the final definition. This allows for a more flexible definition that encompasses a broader range of potential fraud types. “Willful” and “intentional” are not needed because *organic fraud* is not used for enforcement; it is used to help explain the objective of this final rule and many of its provisions.

(Comment) Comments asked AMS to remove “for illicit economic gain,” claiming that not all fraud is illicit or economic in nature. Comments also asked AMS to harmonize the definition of *organic fraud* with terms used by other standards organizations such as ISO, GFSI, FDA, and the EU.

(Response) Many of the organizations mentioned in public comment focus on “economic gain” as a key factor in defining fraud. The final rule does not include the phrase “for illicit economic gain” because not all fraud results in or is motivated by economic gain. This definition is more flexible and encompasses a broader range of potential fraud types than terms used by other standards organizations.

Recordkeeping

(Comment) Comments requested that the regulatory text explicitly allow use of abbreviations for indicating organic status on records.

(Response) AMS amended § 205.103(b)(3) to allow use of similar terms such as acronyms or abbreviations for identifying organic status on audit trail documentation. Abbreviations or acronyms should be easily understood to meet the requirement that all records “be readily understood and audited” (§ 205.103(b)(2)).

(Comment) Comments are concerned that the requirement to identify organic products as such on all records will add an unnecessary recordkeeping burden that duplicates existing recordkeeping or inventory management systems.

(Response) The requirement to identify products as “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” has been revised to apply only to audit trail documentation. Other records should also indicate organic status to meet the requirement that all records “be readily understood and audited” (§ 205.103(b)(2)). However, operations may use a system of recordkeeping or inventory management system that uses lot codes, batch numbers, or other designation system that indicates organic status, as long as such designations are clear and auditable.

(Comment) Commenters requested clarity on the use of “internal” vs. “external” records for purposes of supply chain traceability.

(Response) The requirements of § 205.103(b)(2) applies to broadly all records maintained by an operation, including both “external” and “internal” records. Section 205.103(b)(3) applies only to audit trail documentation, i.e., “external” or “transaction” records.

Fraud prevention plans

(Comment) Comments asked AMS for more detail about the scope of fraud prevention plans and what elements should be included in them.

(Response) The preamble of this rulemaking describes best practices that operations may use to develop and implement fraud prevention plans. The final regulatory text does not include specific practices or requirements; this provides maximum flexibility for operations and certifying agents to determine what is appropriate for individual operations. A fraud prevention plan must describe the operation’s monitoring practices and procedures they use to verify suppliers, verify products received, and prevent organic fraud. The plan must be appropriately tailored to the activities, scope, and complexity of the operation.

(Comment) Comments stated that the fraud prevention plan requirement would cause a disproportionate burden (i.e., greater cost) on small operations, especially small producers.

(Response) The final rule regulatory text and the preamble explain that an operation’s fraud prevention plan must be appropriate to the operation’s complexity, scope, and activities. This may allow operations with less complex activities and/or a more limited scope to write and implement simpler fraud prevention plans.

Supply chain traceability audits

(Comment) Comments requested greater clarity about the proposed rule’s use of the terms traceback, mass-balance, and supply chain audits.

(Response) Verification of traceability back to the last certified operation and mass-balance audits are routine practice during on-site inspection of certified operations. Section 205.403(d)(4)–(5) describe the use of these mechanisms. In contrast, supply chain traceability audits are triggered by criteria defined by the certifying agent. A supply chain traceability audit generally encompasses at least a portion of a supply chain and is conducted to verify the compliance of a product with the organic regulations and the Act.

“Traceback” is a term commonly used in the organic industry. However, this term was used inconsistently in public comment and there was no clear preference for how to define it. Therefore, AMS has avoided using this term in the final rule. AMS defines and uses the term *supply chain traceability audit* to describe certain activities, and the regulatory text clarifies the extent of other traceability requirements (e.g., § 205.103(b)(2)) requires that an operation’s records must be traceable back to the last certified operation).

(Comment) Comments asked AMS for clarification about the phrase “back to the source” in the proposed rule’s revision to § 205.501(a)(21).

(Response) This phrase is not used in the SOE final rule. The length and extent of supply chain traceability audits will vary depending on the objective and findings of the process. Some supply chain traceability audits may extend back to the site of production, while others may only go a few steps back in a supply chain; the audit ends when its objective (e.g., verification of compliance) is achieved.

(Comment) Many comments discussed the administrative impacts of supply chain traceability audits: a few comments claimed some certifying agents may not have the

capacity or expertise to conduct audits; others highlighted challenges with information sharing and coordination among certifying agents.

(Response) Supply chain audits are an important tool for oversight in the organic market. AMS has added flexibility for certifying agents to define the conditions for when supply chain audits are necessary. Further, there are other requirements in this rule that will support supply chain audits: certification of additional handlers in supply chains, mandatory NOP Import Certificates, identifying organic products on audit trail documentation, and information sharing among certifying agents.

Q. Technical Corrections.

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final Regulatory Text
205.301	Product composition. Paragraphs (f)(2) and (3).
205.400	General requirements for certification. Paragraph (b).
205.401	Application for certification. Paragraph (a).

AMS has revised § 205.301 to correct a technical error in the description of the prohibition of ionizing radiation and sewage sludge. A previous technical correction (80 FR 6429) contained an error in the language used to describe the prohibition on ionizing radiation and sewage sludge. The terms “produced” and “processed” were erroneously used to describe the use of ionizing radiation and sewage sludge, respectively, in the current regulatory text. This action corrects the language at paragraphs (f)(2) and (f)(3) to clarify that all products labeled as “100% organic” or “organic” and all ingredients identified as organic in the ingredient statement of any product must not be processed using ionizing radiation or produced using sewage sludge.

AMS also revised §§ 205.400(b) and 205.401(a) to correct the references to organic system plans (§ 205.201), which was incorrectly cited in the previous organic regulation.

R. Additional Amendments Considered but not Included in this Rule.

The Strengthening Organic Enforcement proposed rule asked the public for feedback on two additional subjects: packaged product labeling and expiration of certification.

AMS did not propose amending the portions of the USDA organic regulations that relate to these subjects. The specific questions asked in the proposed rule were meant to elicit feedback from stakeholders about the two topics for possible future consideration. AMS has summarized the public comment received below.

Summary of public comments: packaged product labeling

Processed and/or packaged food products are often manufactured or packaged by one business and labeled for sale/distribution by another business. This type of relationship, sometimes called contract manufacturing and private labeling, is common in both the organic and nonorganic markets. This rulemaking does not change how such products are labeled for retail sale. However, in the proposed rule AMS asked for public comment on private-labeled product labeling, prompting feedback about preferred terminology and which businesses should be listed on labels.

Overall, there was no consensus among comments about issues of organic private-labeled products, including who should be certified, what terminology to use, and which operations and certifying agents should be listed on labels. Because private label and brand/contract relationships are on a contract-by-contract basis to protect proprietary information, some comments argued that creating a single set of rules to govern these relationships may change how private labels operate in the future. The comments received reflect this, and include a variety of opinions based on a commenter's position in the organic supply chain. Responses from public comments are summarized below along with background information to provide context and help explain comments.

Preferred terminology to describe private label products and parties

Throughout the supply chain there are many steps where brand companies can leverage contracted companies to produce items for sale under the brand. After raw material sourcing, there are opportunities for a company to contract out steps such as manufacturing, packaging, and distribution.

Because of the variable use and function of contracted organizations in organic production, it is important to use common terminology to refer to organic operations and their certifying agents. Many comments requested consistent regulatory terminology to categorize these operations in relation to the organic supply chain, but there was no clear preference for certain terminology. Terms and relationships between contract food producers and brand owners are highly variable in the organic industry, but comments highlighted opportunities to align with commonly used and understood terminology. Comments suggested terms that could be consistently used to prevent confusion about which companies should appear on product labels, including contract manufacturer or “co-man,” contract packer or “co-packer,” external distributors, Private label entities/owners, and brand owners.”

Listing contract manufacturers on labels

The SOE proposed rule asked the public if private label products or brands that use contract manufacturers should list those manufacturers on the product label. The majority of comments supported optionally listing contract manufacturers. Those who did not agree with this opinion requested that products should list the brand name and the contract manufacturer. Currently, it is mandatory for some product categories such as meat, poultry, and dairy to have an Establishment Number that can trace back to the facility where it was processed. For other products that are not currently mandated to provide this information, identity of the contract manufacturer is often considered

proprietary information, and in some instances, there could be multiple contract manufacturers operating at the direction of one brand owner.

Commenters were concerned that listing contract manufacturers would result in a loss of competitiveness; mandatory listings would expose proprietary information and undercut the success of these relationships. For brand owners that use several contracted companies, their products would need multiple versions of labels and traceability would become more complex. Comments also questioned the purpose of listing contract manufacturers on labels, some arguing that it would not improve organic integrity or traceability, especially because certifying agents are already listed on products. Some comments discussed that certifying agent information is enough to trace the product back to the manufacturer, making the listing of contract manufacturers unnecessary.

Listing certified operations on private-label packaged products

The organic regulations currently require listing a certified operation on branded products. The proposed rule asked commenters which certified operations should be added to the packaging of private label products, in the interest of furthering traceability. Many comments recommend the brand owner/distributor and their certifying agent be listed on retail labels, with some comments stating no preference. Some commenters stated listing the brand owner would require companies to impose traceability standards on the contract companies they use.

Some individuals recommend listing the last certified operation in the supply chain, to improve clarity and traceability, while others contradict this point by discussing the confidentiality concerns of listing the contract manufacturer. Commenters noted that distributors may be the best certified operation to list because they are often the last step in the organic handling process and can trace a product back through manufacturing and sourcing. Conversely, others noted that not all companies handle distribution internally (choosing instead to use a contracted company).

Other comments claim that listing co-packers on labels is not necessary if brand owners are certified; however, some comments indicated it is unclear if brand owners need to be certified. Finally, a few comments recommended AMS assess the labeling requirements' alignment with the FDA.

Listing certifying agents on private-label packaged products

Multiple certifying agents are typically involved in the production and processing of organic products (from raw materials to material refining, manufacturing, and distribution); each assures that an individual process or step meets the organic standard. In the case of brand companies with contract manufacturers, comments did not clearly agree on which certifying agent (that of the brand company or that of the contract manufacturer) to list on the product label. Many individuals supported listing the certifying agent of the brand owner/distributor, but the brand owner may not be certified. For example, some comments pointed out that retailers are often the brand owners/distributors of organic products, but they are often exempt from organic certification. In this case, some commenters recommended listing the contract manufacturer's certifying agent.

Others recommended listing the certifying agent that certified that last handling operation in the supply chain, arguing that this would aid traceability. However, due to the variety of different manufacturing/ branding relationships, this could be either the certifying agent of the brand owner or the manufacturer.

Matching the certifying agent to the listed operation

Organic product labels currently must include both a certifying agent and an operation. Commenters generally agreed that if a specific operation is listed (i.e., contract manufacturer), that the certifying agent on the label should match. Comments explained that matching the two organizations would make it easier to contact a responsible party or file a complaint. Commenters on the proposed rule also agree that a

label that lists the brand name next to the contract manufacturer's certifying agent would be confusing. However, given that some brand owners may not be certified, commenters noted this mismatch may already be happening in the marketplace.

Summary of public comments: expiration of certification

Under current USDA regulation, organic certification continues until surrendered, revoked, or suspended (§ 205.404(c)). Certified operations must undergo an annual recertification process (§ 205.406), but certification does not expire after one year. While developing the SOE proposed rule, AMS considered, but did not propose, adding a mechanism where certification would expire if an operation did not complete the annual recertification process timely.

The proposed rule included specific questions about expiration of certification and asked the public to comment on the subject. At this time, AMS has chosen not to pursue a policy of expiration of certification. The following is a summary of public comments received in response to the questions AMS asked the public in the SOE proposed rule.

Potential improvements to organic integrity

The SOE proposed rule asked the public how annual expiration of certification could improve organic integrity. Some comments suggested that expiration could be an incentive for operations to punctually renew. Some comments adverted that it may help address the common incident of adverse action circumstances by encouraging operations to update their (organic system plan) OSP and pay fees on time. Commenters expressed if operations understood the annual expiration date, operations with unresolved noncompliances would risk losing certification via expiration. Those who did not agree indicated that current regulation specifies that operations are certified unless suspended or revoked. The annual expiration would disrupt this current system of recertification.

Limitations of expiration of certification

The proposed rule requested the public to comment on what the limitations of requiring expiration of certification may be. Commenters forecast potential negative effects such as marketplace disruption, communication burdens and administrative burdens. Commentators mentioned that expiration may negatively impact the status of inventory of operations who allowed their certification to expire. One remark stated that the requirement could place additional administrative burden on the certifying agent: expiration of certification would result in the certifying agent having to update systems, train staff, educate operations on the policy change, and frequently remind operations of the upcoming expiration date.

Minimum requirement for renewing certification

The SOE proposed rule asked for comments on what the minimum requirement for renewing certification should be. Many commenters recommended the following process: submit required paperwork, pay annual fee, and confirm interest in renewing. It was also recommended that on-site inspection should not be a requirement for recertification.

Operations with adverse actions

The proposed rule asked the public if an operation with adverse actions that are in the appeals process could renew certification. Comments expressed contrasting views on this matter, some finding that operations should be able to renew, and some communicating that those operations should not have the flexibility to renew their certification. Some comments pointed out that the appeal process for a proposed suspension is lengthy, and that not allowing an operation with pending adverse actions to renew certification would promptly remove them from the system and prevent potentially noncompliant product from entering the market. Some individuals stated that depending on the severity of the pending adverse action, AMS should administer a system that

would not block an operation from renewing its certification due to minor non-compliances. Others asked that if an operation has a record of failing to address certain adverse actions, then the system should prevent them from renewing their certification.

Grace period for renewing certification

The SOE proposed rule asked commenters if a grace period would be appropriate for operations that failed to renew by the expiration date. Commenters were also asked what the length of the grace period should be. Overall, comments proffered a 30- or 90-day grace period or mentioned that the current system already has a grace period built into the timeline. Some individuals suggested that a grace period would improve assurance among farmers.

Process of regaining certification

The SOE proposed rule asked the public to express their opinion on what process should exist for an operation to regain organic certification should they allow it to expire. Many individuals communicated that the process of regaining an expired certification should be different than regaining a suspended/revoked certification. They stated the process should also be dependent on the presence and severity of adverse actions and there should be leniency within the duration. Some commentators proposed that operations with expired certification should apply as a new applicant, unless applying within the grace period. However, a commenter identified a potential loophole in tracking pending adverse actions of operations with expired certification; they recommended a system that would keep a record of operations with any pending adverse actions.

Notification of upcoming expiration of certification

The SOE proposed rule asked the public if certified agents should notify certified operations of their upcoming expiration of certification. Commenters clarified that notifying certified operations is currently a widespread practice. Moreover, a commenter

suggested that notification should be sent from the Organic Integrity Database, which may normalize the process.

IV. Regulatory Analyses

A. Summary of Economic Analyses

Executive Orders 12866 and 13563 control regulatory review.⁵⁶ Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives, and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market.

This rulemaking amends amending several portions of the USDA organic regulations (7 CFR Part 205) to strengthen oversight and enforcement of the production, handling, sale, and marketing of organic agricultural products in the United States. The amendments address gaps in the organic standards to deter organic fraud and create a level playing field for farms and businesses. This reinforces the value of the organic label by assuring consumers and stakeholders that organic products meet a robust and consistent standard.

⁵⁶ Executive Order 12866, Regulatory Planning and Review, September 30, 1993: <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf>
Executive Order 13563, Improving Regulation and Regulatory Review:
<https://www.federalregister.gov/documents/2011/01/21/2011-1385/improving-regulation-and-regulatory-review>

The revised organic standards in this rule affect: certifying agents; certified operations (farms, processors, and handlers); and certain operations that are currently excluded or exempt from organic certification (e.g., certain brokers, traders, importers, exporters).

The following discussion summarizes the economic analysis AMS performed to estimate the impacts of this rule. A complete economic analysis of this rulemaking is available at <https://www.regulations.gov/>. You can access the economic analysis by searching for document number AMS-NOP-17-0065.

B. Regulatory Impact Analysis

The costs of this rule are primarily due to new or additional reporting and recordkeeping (paperwork) activities. In addition, there is cost for some currently excluded and exempt operations to become certified to handle organic products. AMS estimated the benefits of this rule by quantifying the organic fraud that will be prevented by implementation of the rule. The estimated benefits are expected to outweigh the estimated costs. Total estimated costs and benefits of the rule are summarized below.

Costs and Benefits of Rulemaking Discounted at 3% and 7%				
Amendments	Average Annual Cost^a		Total Cost^b	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Domestic Certifying Agents				
Imports to the United States	\$50,247	\$37,534	\$753,710	\$563,016
Certificates of Org. Operation & Cont. of Certification	\$22,742	\$21,892	\$341,130	\$328,377
Personnel Training & Qualifications	\$144,661	\$108,061	\$2,169,922	\$1,620,918
On-Site Inspections	\$96,402	\$72,012	\$1,446,031	\$1,080,176
Supply Chain Traceability & Organic Fraud Prevention	\$4,089	\$3,054	\$61,333	\$45,815
Mediation	\$139	\$134	\$2,091	\$2,013
Domestic Excluded Handlers				
Applicability and Exemptions	\$8,349,390	\$6,236,939	\$125,240,844	\$93,554,079

Imports to the United States	\$369,807	\$276,243	\$5,547,100	\$4,143,647
Domestic Certified Operations				
Labeling of Nonretail Containers	\$901,966	\$673,763	\$13,529,496	\$10,106,444
Supply Chain Traceability & Organic Fraud Prevention	\$609,066	\$454,968	\$9,135,993	\$6,824,526
Total Costs and Benefits, Discounted Over 15 Years				
Total Expected Domestic Costs	\$10,548,510	\$7,884,601	\$158,227,651	\$118,269,011
Total Expected Foreign^c Costs	\$8,769,681	\$6,550,892	\$131,545,210	\$98,263,398
Total Expected Domestic & Foreign Costs	\$19,318,191	\$14,435,494	\$289,772,861	\$216,532,409
Total Expected Benefit of Rulemaking	\$32,944,811	\$24,272,099	\$494,172,179	\$364,081,491

^a These are the estimated annual averages of the 15-year Net Present Value domestic costs discounted at 3 and 7 percent.

^b These are the estimated total domestic costs for affected industry in Net Present Value of the stream of future costs, discounted at 3 and 7 percent.

^c AMS assumes all foreign costs will pass through to U.S. consumers and therefore includes these costs in the final rule. See the full Regulatory Impact Analysis for more detail.

Estimation of Benefits

AMS expects that this rule will reduce organic fraud in the U.S. market. Therefore, AMS quantified the estimated benefits of the rulemaking as the value of the projected reduction in organic fraud in the U.S. organic marketplace following implementation. AMS reviewed economic studies that identify and quantify fraudulent activity in retail food markets. AMS then used these estimates of fraud as a benchmark to quantify the benefits of the rulemaking.

Based on analysis of these food fraud studies, AMS estimated that 2 percent of organic products sold in the United States are currently subject to some form of fraud. This estimate aligns with rates of food fraud reported in multiple studies. Therefore, AMS estimated the total value of organic fraud in the United States as 2 percent of the total annual organic premiums for domestic organic production and organic imports, or approximately \$109 million annually. AMS chose to use organic premiums (the cost difference between organic and nonorganic products) to estimate fraud because this more

accurately measures the value lost to fraud than total sales value (i.e., a fraudulent organic product only loses the value of its organic attributes, not its entire value as a food product).

AMS expects the changes from this rule will reduce the amount of organic fraud (estimated at \$109 million annually) by half (an estimated \$54 million). However, it is unclear what proportion of this \$54-million fraud reduction translates directly into social welfare loss. For example, some certified operations and other compliant entities in organic supply chains may unknowingly experience some economic gain from fraud elsewhere in the supply chain. Additionally, AMS cannot accurately predict how fraud reduction efforts would impact organic prices, and hence premiums. Given this uncertainty about the true value of social welfare loss, AMS reduced the estimated \$54 million fraud reduction by half for an estimated social welfare gain (benefit) of \$27 million in the first year following implementation of the rule. Estimated over a 15-year period, and accounting for projected future annual growth rates of the U.S. organic market, annual benefits from fraud reduction are estimated to reach \$57 million in year 2036. When discounted over the 15-year period, total economic benefits of the rulemaking range from \$364 to \$494 million. When averaged, the economic benefits range from \$24.3 to \$32.9 million annually.

Estimation of Costs

The costs of this rule are driven primarily by new or additional reporting and recordkeeping (paperwork) activities. AMS estimated additional paperwork cost for each provision of the rule by identifying the affected population (e.g., number of producers affected by a change), estimating the time for each affected entity to comply with a new change, and assigning an appropriate labor category and wage rate. This accounting of new reporting and recordkeeping costs is discussed in more detail in the Paperwork Reduction Act section of this rulemaking.

This rule would also require some currently excluded and exempt operations to become certified to handle organic products. AMS predicts that these businesses fall within NAICS categories 425 (*Wholesale Electronic Markets and Agents and Brokers*) and 4244 (*Grocery and Related Product Merchant Wholesalers*). These categories are very broad and include mostly businesses that do not handle organic products. Therefore, AMS used participation rates in the organic sector to estimate that 1,985 domestic businesses would need to become certified organic. Using historic knowledge of certification costs, AMS estimated that each of the affected 1,985 domestic businesses would spend \$2,000 to become certified organic.

AMS also estimated the cost of this rule to foreign entities, including both paperwork and recordkeeping burden and costs for certain businesses to obtain certification. AMS assumes that all foreign costs will be passed along to U.S. consumers. This may create some tendency to overstate U.S.-borne costs, as competitive pressures will lead some compliance costs to be absorbed by businesses and other entities as the cost of doing business.

Alternatives

AMS also considered three alternatives when developing this rulemaking.

1. Make no change to the organic regulations. This option would not implement this rulemaking and leave the organic regulation as-is. AMS did not select this option because it does not address organic fraud or other issues affecting organic integrity. AMS considers this a costly alternative because it forgoes the fraud reduction benefits of the rulemaking. Regulatory inaction would create social costs that increase over time. AMS believes the rulemaking will mitigate social welfare losses by approximately half through the use of practical, risk-based oversight and enforcement.

2. Require NOP Import Certificates for individual imported shipments of organic product. The rulemaking will allow NOP Import Certificates to be issued for multiple

shipments over a time span to be determined at the discretion of each certifying agent. In contrast, this alternative would require the use of NOP Import Certificates for each physical shipment of organic products imported into the United States. AMS found this alternative to be inferior to the rulemaking because it would create greater cost with limited additional benefit. AMS believes that the rulemaking's option to issue NOP Import Certificates on a periodic basis is the most practical, effective, and cost-sensitive means to address fraudulent imported organic products.

3. Require less-stringent data reporting and training requirements for certifying agents. AMS also considered a less-stringent alternative to the rulemaking to assesses if this could lower costs while maintaining the effectiveness of the rulemaking. Relative to the rulemaking, this alternative would (1) omit the requirement for certifying agents to issue standardized certificates of organic operation generated in the USDA Organic Integrity Database; and (2) reduce the annual training hours that must be completed by organic inspectors and certification review personnel. AMS chose not to pursue this alternative because it would weaken other critical, interdependent amendments in the rulemaking. AMS predicts any cost reduction of this alternative would be accompanied by a significant reduction in effectiveness of the rulemaking.

Regulatory Flexibility Act

AMS also performed additional analysis to determine the rule's impact to domestic small businesses. This analysis revealed that small businesses producing, selling, handling, and marketing organic products would not be adversely affected by the amendments in this rule. AMS expects that most of the entities affected by this rule are small businesses as defined by Small Business Administration criteria. For each category of affected entity (certifying agents, certified operations, and exempt or excluded operations that need to become certified), AMS estimates that the costs of the rule for each business type will be less than one percent of the annual revenue.

A full economic analysis of this rulemaking is available at <https://www.regulations.gov/>. You can access this rule and the economic analysis by searching for document number AMS-NOP-17-0065.

C. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This rule cannot be applied retroactively. States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 6507(b)(2) of the OFPA, a state organic certification program that has been approved by the Secretary may contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state under certain circumstances. Such additional requirements must (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to section 6519(c)(6) of the OFPA, this rulemaking does not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the

Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301-399), nor the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136-136(y)).

OFPA at 7 U.S.C. 6520 provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

D. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA), AMS is requesting OMB approval for a new information collection totaling 368,321 hours for the reporting and recordkeeping requirements contained in this rulemaking. OMB previously approved information collection requirements associated with NOP and assigned OMB control number 0581-0191. AMS intends to merge this new information collection (0581- 0321), upon OMB approval, into the approved 0581-0191 collection. Below, AMS has described and estimated the annual burden (i.e., the amount of time and cost of labor), for entities to prepare and maintain information to participate in this voluntary labeling program. The Organic Foods Production Act of 1990 (OFPA) provides authority for this action.⁵⁷

Title: National Organic Program.

⁵⁷ The Organic Foods Production Act of 1990, 7 U.S.C. 6501–6524, is the statute from which the Agricultural Marketing Service derives authority to administer the NOP, and authority to amend the regulations as described in this rulemaking. This document is available at: <https://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter94&edition=prelim>

OMB Control Number: 0581- 0321.

Expiration Date of Approval: 3 years from OMB date of approval.

Type of Request: New collection.

Abstract: Information collection and recordkeeping are necessary to implement reporting and recordkeeping necessitated by amendments to §§ 205.2, 205.100, 205.101, 205.103, 205.201, 205.273, 205.300–205.302, 205.310, 205.307, 205.310, 205.400, 205.403–205.404, 205.406, 205.500–501, 205.504, 205.511, 205.660–205.663, 205.665, 205.680, and 205.681 of the USDA organic regulations. The rulemaking will protect organic product integrity and build consumer and industry trust in the USDA organic label by strengthening organic control systems, improving organic import oversight, clarifying organic certification standards, and enhancing farm to market traceability.

This rulemaking amends several sections of the USDA organic regulations, 7 CFR Part 205, to strengthen the NOP’s ability to oversee and enforce the production, handling, marketing, and sale of organic agricultural products as established by the OFPA. The rule will improve organic integrity throughout the organic supply chain and benefit stakeholders at all levels of the organic industry. The amendments will close gaps in the current regulations to build consistent certification practices, deter organic fraud, and improve transparency and product traceability. NOP identified the need for many of the amendments as part of its direct experience in administering this program, particularly via complaint investigation and audits of certifying agents. Other amendments are based on changes to the OFPA included in the Agriculture Improvement Act of 2018;⁵⁸ the recommendations of a 2017 Office of Inspector General audit;⁵⁹ the recommendations of

⁵⁸ The Agriculture Improvement Act of 2018 (Public Law No: 115-334), commonly known as the “2018 Farm Bill,” is available at <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>. Organic certification is discussed in Title X, Section 10104.

⁵⁹ The National Organic Program International Trade Arrangements and Agreements Audit Report 01601-0001-21, September 2017: <https://www.usda.gov/sites/default/files/01601-0001-21.pdf>

the National Organic Standards Board (a federal advisory committee to NOP); and industry stakeholder feedback.

This rulemaking strengthens enforcement with amendments to the USDA organic regulations and modifies the reporting and recordkeeping burdens as summarized below.

1. Reduces the types of uncertified handling operations in the organic supply chain that operate without USDA oversight.⁶⁰ The amendments require certification of operations that facilitate the sale or trade of organic products, including but not limited to certain brokers, importers, and traders. These handlers must obtain organic certification and develop an organic system plan (OSP) to describe the practices and procedures used in their operations. Certifying agents customize the format of the OSP to cover standards applicable to operations seeking certification. Because traders and brokers do not farm or manufacture organic products, the OSPs for traders and brokers will address fewer sections of the organic regulations than OSPs for operations that farm or manufacture organic products. Therefore, uncertified traders and brokers will take 40 hours in the first year after the rule going into effect to prepare an initial OSP. In subsequent years, AMS estimates each of these entities will incur a recordkeeping burden of 10 hours annually, and a reporting burden of 20 hours annually, to update their OSP (§§ 205.2, 205.100, 205.101, and 205.103).

Burden is increased in the rulemaking due to refinements in NAICS code 425 and the addition of operations from NAICS code 4244 in response to public comment. The 2018 Farm Bill mandates that NOP reduce the number of operations excluded from certification at § 205.101. AMS's revised estimate indicates 1,985 formerly excluded domestic operations now require organic

⁶⁰ Mandated by the Agriculture Improvement Act of 2018. See section 10104(a).

certification. This includes 855 operations in NAICS code 425 (*Wholesale Electronic Markets and Agents and Brokers*) and 1,130 operations in NAICS code 4244 (*Grocery and Related Product Merchant Wholesalers*). See the accompanying Regulatory Impact Analysis (RIA) for more information. AMS assumes the 1,985 domestic excluded operations represent 59 percent of the global total of excluded handlers (using a benchmark 59 percent to 41 percent ratio of domestic to foreign operations). Therefore, AMS estimates there are an additional 1,379 foreign formerly excluded operations, for a total of 3,364 new handlers that will need organic certification.

2. Requires all currently certified organic operations and new applicants to describe their procedures for monitoring, verifying, and demonstrating the organic status of their suppliers and products received to prevent organic fraud. Operations will include this information as a supplemental part of the OSP; therefore, AMS allocates the time to develop these procedures separately from the initial 40 hours to develop an OSP. AMS estimates that each currently certified operation and applicant seeking certification will need 30 minutes to describe the supply chain verification procedures and monitoring practices required by this regulation (§§ 205.103 and 205.201). Burden is increased in the rulemaking due to industry growth.
3. Mandates the use of NOP Import Certificates. Each shipment of organic products imported into the United States must be declared as organic to U.S. Customs and Border Protection (CBP) and associated with a valid NOP Import Certificate (currently form NOP 2110-1).⁶¹ The NOP Import Certificate contains specific information about the quantity and source of a shipment of imported organic

⁴⁹ Office of Management and Budget (OMB)-approved form NOP 2110-1 NOP Import Certificate: <https://www.ams.usda.gov/resources/nop-2110-1>

products. NOP Import Certificates are currently used for organic products imported from countries with which NOP has trade arrangements. This rulemaking will expand and make compulsory the use of NOP Import Certificates, regardless of an imported product's country of origin.

In response to public comments, the final rule allows NOP Import Certificates to be issued for a given time period (e.g., quarterly) rather than with every shipment as proposed. AMS estimates that NOP Import Certificates will be issued quarterly, as this will reduce costs and limit disruption to the speed of imports. Additionally, the estimated number of annual shipments has increased from 67,023 in 2017 to 80,109 in 2020 due to industry growth.⁶² Therefore, AMS estimates 3,856 exporters will request from their certifying agents an annual total of 15,424 NOP Import Certificates, covering 80,109 annual shipments.⁶³ AMS estimates each exporter and certifying agent will spend an average of 30 minutes to request and approve each NOP Import Certificate. This estimate accounts for some learning within the first year, as well as the option to issue a single NOP Import Certificate for multiple shipments over a specific timeframe and amount or volume. Additionally, AMS estimates that importers and their certifying agents will need an average of one tenth (0.1) of an hour, or 6 minutes, to compare the shipping manifest of each shipment with its respective NOP Import Certificate to verify the accuracy and organic compliance of each shipment.

⁶² Data source: USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS). Select: Partners, World Total, Product Type, Imports—General, Products: All Aggregates; Product Groups: Organic—Selected: <https://apps.fas.usda.gov/gats/default.aspx>

⁶³ NOP International Division reports that 3,303 organic exporters are certified by foreign (non-USDA) certifiers. Plus, the Organic Integrity Database shows that 553 foreign-based handlers are certified by USDA-accredited certifying agents. The total number of NOP Import Certificates assumes each exporter is issued NOP Import Certificates quarterly (four annually).

Further, certifying agents must have and implement a documented organic control system for intaking and approving or rejecting the validity of an NOP Import Certificate request, and importers must have and implement a documented organic control system to verify that shipments of organic products are accompanied by accurate NOP Import Certificate data and have not had contact with prohibited substances or ionizing radiation (§§ 205.273 and 205.300).

4. Clarifies nonretail containers used to ship or store organic products must display organic identification and information that links the container to audit trail documentation. This will help maintain the integrity of organic products by reducing misidentification and mishandling, facilitating traceability through the supply chain, reducing organic fraud, and allowing accurate identification of organic product by customs officials and transportation agents.

The rulemaking reduces burden because the revised regulation requires less information on nonretail container labels and provides exceptions for certain types of containers in response to public comment. AMS estimates that 35,698 producers and/or processors will need one tenth (0.1) of an hour, or 6 minutes, to add the required information to the labels that are displayed on the nonretail containers of an estimated 275,596 annual shipments (§ 205.307).⁶⁴

5. Codifies current practices for the certification of producer group operations (groups of producers organized and certified as a single operation).⁶⁵ The rulemaking describes the criteria to qualify as a producer group, how producer group operations must comply with the USDA organic regulations, and how

⁶⁴ 29,929 (existing and new domestic operations and traders) certified operations will be modifying how they label 195,387 nonretail shipments and 5,769 (existing, new, and domestic operations and traders) certified operations will be modifying how they label 80,109 nonretail shipments exported to the US.

⁶⁵ NOP Policy Memo 11-10. Grower Group Certification, October 31, 2011: <https://www.ams.usda.gov/sites/default/files/media/NOP-11-10-GroupGrowerCert.pdf>

certifying agents should inspect these operations. It also sets a risk-based benchmark to determine how many producer group members in an operation need to be inspected by certifying agents annually.

In response to public comment, AMS expects that these requirements will add 11,800 hours of one-time paperwork burden for 5,900 producer group operations⁶⁶ to prepare a detailed Internal Control System for their OSP, including procedures to address conflicts of interest and manage the unique challenges of producer group oversight. In addition, AMS estimates 5 hours to prepare and deliver training, outreach and technical assistance to ICS personnel and producer group members, leading to a total annual burden of 29,500 hours of burden annually (§§ 205.201, 205.400(g) and 205.403).

6. Clarifies how certified operations may submit annual updates to their OSP. This includes the option to only submit practices or procedures that have changed since their last approved OSP, rather than submitting an OSP in its entirety. This will reduce unnecessary paperwork without compromising oversight because operations will continue to maintain an OSP that accurately reflects current practices and procedures of the operation. This codifies current policy and does not modify the paperwork burden (§ 205.406).
7. Requires certifying agents to issue standardized certificates of organic operation generated from the USDA's publicly available Organic Integrity Database (OID).⁶⁷ This will require an initial upload of mandatory data for each operation and maintenance to ensure that data in OID are current and accurate. Currently, all certifying agents have voluntarily uploaded data and maintain an estimated

⁶⁶ Meinshausen F., Richter, T., Blockeel, J., and Huber, B., Group Certification: Internal Control Systems in Organic Agriculture: Significance, Opportunities and Challenges, Research Institute of Organic Agriculture FiBL, March 2019.

⁶⁷ Organic Integrity Database: <https://organic.ams.usda.gov/integrity>. Accessed September 2021.

50% or more data on all certified operations per the recommendations found in the NOP's Data Quality Best Practices.⁶⁸

These amendments will require a new, one-time burden of reporting hours for certifying agents to upload existing data pertaining to currently certified operations into OID for the first time. It is estimated that uploading these data into OID will require 30 minutes for each operation and will be performed by administrative support personnel who have a lower wage rate than review and compliance staff. The rulemaking's burden increases slightly due to industry growth.

These amendments will simultaneously eliminate the requirement to physically mail the Administrator or State organic program paper copies of: (1) the list of operations certified annually; (2) notifications of proposed adverse actions, approvals, or denials of corrective actions; and (3) notifications of executions of adverse actions regarding certified operations or operations applying for certification (§§ 205.405 and 205.501). AMS is not modifying the estimate of paperwork burden associated with these changes in requirements because any change will be very small, and these activities and tasks are still occurring electronically as a part of maintaining the data on all operations over time.

8. Requires certifying agents to develop procedures to: (1) identify high-risk operations and agricultural products; (2) conduct supply chain traceability audits, (3) share information with other certifying agents to verify supply chains and conduct investigations, and (4) report credible evidence of organic fraud to the USDA. Due to the complexity of these procedures, AMS estimates each certifying agent will spend two hours documenting these procedures (§§ 205.501

⁶⁸ Data Quality Best Practices:
<https://www.ams.usda.gov/sites/default/files/media/INTEGRITY%20Data%20Quality.pdf>

and 205.504) rather than one hour as proposed. The rulemaking's burden increases due to an increase in time for preparing procedures despite a net loss of certifying agents since 2017 (the net value reflects that while some certifiers have been suspended or have surrendered, others have been newly accredited).

9. Requires certifying agents to submit their decision criteria for acceptance of mediation, and a process for identifying personnel to conduct mediation and set up mediation sessions with its administrative policies and procedures required by § 205.504(b). AMS estimates each certifying agent will spend one hour documenting these procedures, which they are already implementing. The rulemaking's burden changes due to the net loss of 3 certifying agents since 2017.
10. Requires certifying agents to establish procedures to conduct inspector field evaluations ("witness inspections"), demonstrate that they are sufficiently staffed with qualified personnel, and demonstrate that all inspectors, certification reviewers, and in-field evaluators meet knowledge, skills, and experience qualifications. AMS estimates that each certifying agent will spend 60 minutes to draft policies and procedures for conducting inspector field evaluations. Further, certifying agents must observe an inspector performing an on-site inspection at least once every three years (or annually for inspectors with fewer than three years of experience).

The rulemaking's burden is reduced due to narrowed training requirements and the net loss of 3 certifying agents since 2017. AMS estimates each certifying agent will conduct an average of two field evaluations of an inspector and certification review personnel per year, rather than four as proposed, and that this activity will require 7.5 hours per evaluation (§§ 205.2 and 205.501).

11. Requires some additional training of new inspectors and certification review personnel. Inspectors and certification review personnel play a crucial role in

determining whether an operation is granted organic certification initially and whether certified operations comply with the USDA organic regulations.

Certification review personnel may also serve as inspectors. Through insight gained during regular audits of certifying agents, AMS estimates that inspectors and certification review staff currently receive at least 10 hours of training per year from certifying agents on topics related to the USDA organic regulations.

In response to public comment, 40 hours of additional training is required for inspectors and certification review personnel with less than one year of experience.⁶⁹ Based on an estimated separation rate of 14 percent,⁷⁰ AMS estimates that certifying agents will annually hire 35 new certification review staff and hire or contract with 35 inspectors with less than one year of experience to replace the certification review staff and inspectors that exit the labor pool.

Training offered by NOP through its online Organic Integrity Learning Center (OILC) and training provided by the certifying agents or other providers may qualify towards the minimum annual training requirements (§§ 205.2 and 205.501).

12. Requires that certifying agents conduct unannounced inspections of at least 5 percent of the operations they certify, which is the current recommended practice in NOP Instruction 2609.⁷¹ For the purposes of estimating paperwork impacts, AMS expects that half of the unannounced inspections (2.5% of total inspections) will meet the requirement for a full annual inspection and will not impact current

⁶⁹ Ten hours of training are accounted for in the 2020 Information Collections Renewal for NOP (AMS-NOP-19-0090; OMB Control Number: 0581-0191). Our internal on-site accreditation audit checklist used by our accreditation audit team includes a question on training. With the implementation of this rule, the specific hours of training offered by the 75 certifying agents will be documented.

⁷⁰ The US Bureau of Labor and Statistics reports that the average separation rate (which captures both labor force exits and transfers in occupation) for agricultural inspectors is 14 percent.
<https://www.bls.gov/news.release/jolts.t16.htm>

⁷¹ NOP 2609, Instruction, Unannounced Inspections. September 12, 2012. Available in the NOP Program Handbook: <https://www.ams.usda.gov/sites/default/files/media/2609.pdf>

paperwork burden. The remaining half of the unannounced inspections (2.5% of total inspections) will be limited in scope and target high-risk operations and will not count as a full annual inspection. Examples of targeted, limited-scope unannounced inspections include but are not limited to verifying livestock on pasture or performing targeted mass-balance or traceability audits. AMS estimates that the paperwork impacts associated with these unannounced inspections will average inspectors 5 hours per inspection; half of the estimated 10 hours for a full annual inspection (§ 205.403).

13. Clarifies the process for accepting foreign conformity assessment systems that oversee organic certification in foreign countries.⁷² The OFPA (7 U.S.C. 6505(b)) and the USDA organic regulations provide the authority to establish organic equivalency. The revised regulations describe the criteria, scope, and other parameters for ongoing peer review audits of foreign organic conformity systems to determine whether the United States should continue, revise, or terminate such equivalence determinations. These peer review audits of equivalence determinations occur as needed and will result in new periodic paperwork impacts for foreign governments. The rulemaking's burden is reduced because AMS estimates it will review one foreign government conformity assessment system per year. AMS estimates the reporting impacts for foreign governments when USDA reviews the applicable trade arrangement or agreement to be 60 hours. Since recordkeeping is ongoing requirement, recordkeeping is calculated as 10 hours per year per foreign government. These impacts are comparable to the estimated paperwork impacts for AMS audits of certifying agents (§ 205.511).

⁷² Currently, the United States has established organic trade arrangements with Canada, the European Union, the United Kingdom, Israel, Japan, New Zealand, South Korea, Taiwan, and Switzerland.

Respondents

AMS has identified four primary types of entities (respondents) that will need to submit and maintain information as a result of this rulemaking: certified organic operations; accredited certifying agents; organic inspectors; and foreign governments. Three respondent types—certified operations (producers and handlers), certifying agents, and inspectors—have been identified in a currently approved information collection (0581-0191). To implement a 2018 Farm Bill mandate, AMS is requiring certification of additional types of operations in the organic supply chain and regular audits of trade arrangements or agreements with foreign governments.⁷³ This adds new types of handlers as a subcategory of certified operations and foreign governments as a new type of respondent.

To more precisely understand the paperwork impacts of this rulemaking, AMS has divided the categories of respondents into domestic and foreign, as appropriate, to show the potential impacts on domestic-based versus foreign-based USDA-accredited certifying agents, inspectors, and certified operations, along with foreign-accredited certifying agents, and foreign governments serving as accrediting bodies. For each type of respondent, we describe the general paperwork submission and recordkeeping activities and estimate: (1) the number of respondents; (2) the hours they spend, annually, creating and storing records to meet the paperwork requirements of the organic labeling program; and (3) the costs of those activities based on prevailing domestic and foreign wages and benefits.

Certifying agents

Certifying agents are State, private, or foreign entities accredited by the USDA, or by accreditation bodies of foreign governments with which USDA has a trade arrangement

⁷³ See Section 10104(a) of the Agriculture Improvement Act of 2018, Public Law No: 115-334, available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>.

or agreement. Certifying agents certify domestic and foreign producers and handlers as organic in accordance with the OFPA and the USDA organic regulations. Certifying agents determine whether a producer or handler meets the organic requirements, using detailed information from the operation about its specific practices and on-site inspection reports from organic inspectors.

Currently, there are 75 USDA-accredited certifying agents (down from 78 in 2017) 45 are based in the United States and 30 are headquartered in foreign countries. Both domestic- and foreign-based USDA-accredited certifying agents certify operations based in the United States and abroad. AMS assumes all currently accredited certifying agents evaluate all types of production and handling operations for compliance with the USDA organic regulations and will be subject to the reporting and recordkeeping burdens of this rulemaking. In addition, AMS assumes there are 30 foreign government-accredited foreign-based certifying agents that certify handlers in accordance with the USDA organic regulations and that will issue NOP Import Certificates for organic product shipments to the United States.⁷⁴

Certifying agents of operations that export to the United States must issue NOP Import Certificates for all shipments of organic products being exported. The USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS) showed 80,109 shipments of organic product coming into the United States in 2020 (up from 67,023 in 2017 due to industry growth).⁷⁵ In response to public comments, AMS estimates that NOP Import certificates will be issued seasonally (e.g., quarterly) rather than with every shipment as proposed. AMS estimates that 3,856 foreign exporters will request from their certifying agents an annual total of 15,424 NOP Import Certificates,

⁷⁴ An estimate based on the number of foreign-based USDA-accredited certifying agents.

⁷⁵ Data source: USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS). Select: Partners, World Total, Product Type, Imports—General, Products: All Aggregates; Product Groups: Organic—Selected: <https://apps.fas.usda.gov/gats/default.aspx>

covering 80,109 annual shipments.⁷⁶ AMS estimates each exporter and certifying agent will spend 30 minutes to request and approve each NOP Import Certificate.

Thirty (30) USDA-accredited certifying agents based in foreign countries certify 92% of the foreign operations certified under USDA organic standards. Of the 45 domestic-based USDA accredited certifying agents, 15 certifying agents certify 8% of the foreign operations certified under USDA.⁷⁷ This means that 30 domestic-based USDA-accredited certify agents only certify domestic-based operations that do not import foreign organic products or ingredients. AMS estimates there are 30 foreign-accredited certifying agents that certify foreign operations under trade arrangements.⁷⁸

AMS will review documents regarding imports during the accreditation audits of USDA-accredited certifying agents. AMS estimates 30 minutes for the 3,856 exporters and their certifying agents to prepare and approve each of the 15,424 NOP Import Certificates and one tenth of an hour, or 6 minutes, for importers to verify and reconcile all 80,109 subsequent associated shipments exported to the United States.⁷⁶ USDA-accredited domestic-based certifying agents must work with their foreign-based operations to verify their associated shipments for 8%, or 6,409, of 80,109 annual shipments. USDA-accredited foreign-based certifying agents must work with their foreign-based operations to verify their associated shipments for 46%, or 36,850, of 80,109 annual shipments. Foreign-accredited certifying agents must work with their foreign-based operations to verify 46% of 80,109 annual shipments.

In addition, this rulemaking reduces the current paperwork burden of accredited certifying agents by eliminating the need to provide notices of approval or denial of

⁷⁶ NOP International Division reports that 3,303 organic exporters are certified by foreign (non-USDA) certifiers. Plus, the Organic Integrity Database shows that 553 foreign-based handlers are certified by USDA-accredited certifying agents. The total number of NOP Import Certificates assumes each exporter is issued NOP Import Certificates quarterly (four annually).

⁷⁷ Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>

⁷⁸ An estimate based on the number of foreign-based USDA-accredited certifying agents.

certification to the Administrator following the issuance of a notice of noncompliance or adverse action to an applicant for certification. Also, the rulemaking removes the annual requirement for certifying agents to submit by January 2 an annual list of operations certified. Certifying agents will instead be required to update data in OID for each operation they certify. AMS is not modifying the estimate of paperwork burden with these changes in requirements because any change will be very small. These activities and tasks are still occurring electronically as a part of maintaining the data on all operations over time. Certifying agents must issue organic certificates generated in OID.

In addition, all USDA-accredited certifying agents must write detailed procedures to identify high-risk operations and products they certify and procedures to conduct supply-chain traceability audits. Certifying agents must write fraud prevention and reporting procedures, and mediation procedures per § 205.504(b). Certifying agents must write procedures to demonstrate how they are sufficiently staffed and that all persons who perform certification review activities and on-site inspections (inspectors) are qualified and complying with training requirements for their new certification review personnel. AMS estimates that 14 percent, or 35, new certification review staff with less than one year of experience must complete 40 hours of training in their first year in addition to the baseline training requirement of 10 hours annually already accounted for in the overall program ICR (0191).^{79,80}

This rulemaking increases the overall reporting and recordkeeping burden for certifying agents (See Summary Table 1: *Certifying Agents*). AMS estimates the annual

⁷⁹ Ten hours of training are accounted for in the 2020 Information Collections Renewal for the NOP (AMS-NOP-19-0090; OMB Control Number: 0581-0191). Our internal onsite accreditation audit checklist used by our accreditation audit team includes a question on training. With the implementation of this rule, the specific hours of training offered by our 75 certifying agents will be documented.

⁸⁰ The US Bureau of Labor and Statistics reports that the average separation rate (which captures both labor force exits and transfers in occupation) for agricultural inspectors is 14 percent. <https://www.bls.gov/news.release/jolts.t16.htm>

collection cost per domestic-based USDA-accredited certifying agents will be \$13,511.⁸¹ This cost is based on an estimated 109.23 labor hours per certifying agent per year for staff with certification review responsibilities at \$47.97 per labor hour, including 31.7% benefits, for a total salary component of \$5,229 per year.⁸² The estimated cost for domestic certifying agents also includes 332.55 labor hours per certifying agent per year for administrative support staff to upload data about certified operations to OID at \$24.90 per labor hour, including 31.7% benefits, for a total salary component of \$8,282 per year.⁸³

In addition, AMS estimates the annual collection cost for all domestic-based USDA-accredited certifying agents will be \$608,001. This cost is based on a total of 4,915 hours for all staff with certification review responsibilities at \$47.87 per labor hour, including 31.7% benefits, for a total salary component of \$235,313 for all staff with certification review and procedure writing responsibilities of all domestic-based USDA-accredited certifying agents. The estimated cost for all domestic-based certifying agents also includes 14,965 hours total hours for administrative support staff uploading data about certified operations to OID at \$24.90 per labor hour, including 31.7% benefits for a total salary component of \$372,688.

⁸¹ In this assessment, all domestic labor rates are sourced from the U.S. Bureau of Labor Statistics National Compensation Survey, Occupational Employment and Wages, May 2020: https://www.bls.gov/oes/current/oes_nat.htm. Domestic benefits are based on a Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation, which states that benefits account for 31.7% of total average employer compensation costs, December 17, 2020:

⁸² The labor rate for certification review staff is based on Occupational Employment Statistics group 13-1041, *Compliance Officers*. Compliance officers examine, evaluate, and investigate eligibility for or conformity with laws and regulations governing contract compliance of licenses and permits, and perform other compliance and enforcement inspection and analysis activities not classified elsewhere. Compliance Officers (bls.gov)

⁸³ The labor rate for [administrative support staff is based on](#) Occupational Employment Statistics [group 43-9199, Office and Administrative Support Workers](#), who support general office work and data entry functions. Office and Administrative Support Workers, All Other (bls.gov)

SUMMARY TABLE 1: <i>Certifying Agents</i>						
Respondent Categories	Number of Respondents	Wages + Benefits	Hours per respondent	Cost per respondent type	Total All Hours	Total All Costs
US Based USDA Certifying Agents	45	\$47.87	109.23	\$5,229.17	4,915.36	\$235,312.78
US Based USDA Certifying Agents- data entry	45	\$24.90	332.55	\$8,281.95	14,964.69	\$372,687.76
<i>Subtotal U.S.-Based USDA Certifying Agents</i>	45		441.78	\$13,511.12	19,880.05	\$608,000.54
Foreign-Based USDA Certifying Agents	30	\$34.40	653.80	\$22,493.03	19,614.07	\$674,791.04
Foreign-Based USDA Certifying Agents-data entry	30	\$17.90	346.64	\$6,203.93	10,399.19	\$186,118.00
<i>Subtotal Foreign-Based USDA Certifying Agents</i>	30		1,000.44	\$28,696.97	30,013.26	\$860,909.04
Total USDA Accredited Certifying Agents	75			\$42,208.09	49,893.31	\$1,468,909.58
Foreign (Non-USDA) Accredited Certifying Agents	30	\$34.40	614.17	21,129.51	18,425.07	\$633,885.38
All Certifying Agents	105				68,318.38	\$2,102,794.96

For foreign-based USDA-accredited certifying agents, AMS estimates the annual cost per certifying agent will be \$28,697 per year. This cost is based on an estimated 653.80 labor hours for staff with certification review and procedure writing responsibilities at \$34.40 per labor hour, including 34.63% benefits, for a total salary component of \$22,493 per foreign-based USDA-accredited certifying agent per year. These estimated costs primarily pertain to the issuance and review of NOP Import Certificates. The estimated cost for foreign-based USDA-accredited certifying agents also includes 346.64 labor hours per certifying agent per year for administrative support staff to upload data about certified operations to OID at \$17.90 per labor hour, including 34.63% benefits, for a total salary component of \$6,204 per year.^{84,85}

AMS estimates the annual collection cost for all foreign-based USDA accredited certifying agents will total \$860,909. This cost is based on a total of 19,614.07 hours for all staff with certification review responsibilities at \$24.90 per labor hour, including 34.63% benefits, for a total salary component of \$674,791 for staff with certification review and procedure writing responsibilities of all foreign-based USDA-accredited certifying agents. The estimated cost for all foreign-based USDA-accredited certifying agents also includes 10,399.19 hours total hours for administrative support staff uploading data about certified operations to OID at \$17.90 per labor hour, including 34.63% benefits, for a total salary component of \$186,118.^{86,87}

⁸⁴ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents, which were 70.3% of U.S. labor rates in 2020.

<https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents:

<https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>

⁸⁵ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

⁸⁶ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020.

<https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents:

<https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>

⁸⁷ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

For foreign-accredited certifying agents (non-USDA accredited), AMS estimates the annual cost will be \$21,130 per certifying agent. This cost is based on an estimated 614.17 labor hours per year for staff to issue and review NOP Import Certificates, at \$34.40 per labor hour plus 34.63% benefits. The total for all foreign-accredited certifying agents is estimated to be \$633,885. The cost is based on an estimated 18,425 total hours for all staff involved in the issuance and review of NOP Import Certificates, at \$34.40 per labor hour plus 34.63% benefits.^{88,89}

The total cost for all certifying agents—including the 75 USDA-accredited certifying agents, domestic- and foreign-based, and the estimated 30 foreign-accredited (non-USDA) certifying agents who certify operations that export products to the U.S.—is \$2,102,795. This cost is based on 68,318.38 total hours at their respective wage rates and benefits to comply with the rulemaking's requirements.

Organic Inspectors.

Inspectors conduct on-site inspections of certified operations and operations applying for certification and report the findings to the certifying agent. Inspectors may be independent contractors or employees of certifying agents. Certified operations must be inspected annually, and a certifying agent may call for additional inspections or unannounced inspections on an as-needed basis (§ 205.403(a)). Any individuals who apply to conduct inspections of operations will need to submit information documenting their qualifications to the certifying agent (§ 205.504(a)(3)).

Inspectors provide an inspection report to the certifying agent for each operation inspected (§ 205.403(e)) but are not expected to store the record. Currently, AMS

⁸⁸ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020.

[https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD.agents:](https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD.agents)
<https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>

⁸⁹ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

estimates that inspectors spend 10 hours on average to complete an inspection report for a full annual inspection of an organic operation. The additional unannounced inspections required by this rulemaking are likely to be more limited in scope (such as pasture or dairy surveillance, or mass-balance and supply chain traceability audits). AMS projects, on average, that inspectors will spend 5 hours to complete an inspection report for an unannounced targeted-scope inspection. Organic inspectors do not have recordkeeping obligations; certifying agents maintain the records of inspection reports (see Summary Table 2: *Inspectors*).

SUMMARY TABLE 2: <i>Inspectors</i>						
Respondent Categories	Number of Respondents	Wages + Benefits	Hours per respondent	Cost per respondent type	Total All Hours	Total All Costs
USDA US based Inspectors	148	\$30.79	30.86	\$950.20	4,567.17	\$140,629.94
USDA Foreign based inspectors	102	\$22.13	31.12	\$688.53	3,173.80	\$70,229.73
All USDA Inspectors	250				7,740.97	\$210,859.67

According to the International Organic Inspectors Association (IOIA), there are approximately 250 inspectors currently inspecting crop, livestock, handling, and/or wild crop operations that are certified or have applied for certification. To comply with this rulemaking, AMS estimates that 14 percent, or 35, new inspectors with less than one year of experience must complete 40 hours of training in their first year in addition to the

baseline training requirement of 10 hours annually already accounted for in the overall program ICR (0191).^{90,91}

AMS estimates that 148 inspectors are working for USDA-accredited certifying agents in the United States. For the additional training of new inspectors, and for conducting unannounced targeted-scope inspections, AMS estimates the annual paperwork impact cost per domestic-based inspector is \$950.20. This is based on an estimated 30.86 labor hours per year at \$30.79 per labor hour, including 31.7% benefits. The total annual cost for all domestic-based inspectors is \$140,630. This cost is based on 4,567 total hours for all domestic based inspectors at \$30.79 per labor hour, including 31.7% benefits.⁹²

AMS estimates that 102 inspectors are working for USDA-accredited certifying agents in foreign countries. AMS estimates the annual paperwork impact cost per foreign-based inspector is \$688.53. This estimate is based on an estimated 31.12 labor hours per year at \$22.13 per labor hour, including 34.63% benefits for the additional training of new inspectors and for conducting unannounced targeted-scope inspections. This rule does not impose additional recordkeeping costs for inspectors. The total annual cost for all foreign-based inspectors is \$70,230 at \$31.12 per labor hour, including

⁹⁰ Ten hours of training are accounted for in the 2020 Information Collections Renewal for the NOP (AMS-NOP-19-0090; OMB Control Number: 0581-0191). Our internal onsite accreditation audit checklist used by our accreditation audit team includes a question on training. With the implementation of this rule, the specific hours of training offered by our 75 certifying agents will be documented.

⁹¹ The US Bureau of Labor and Statistics reports that the average separation rate (which captures both labor force exits and transfers in occupation) for agricultural inspectors is 14 percent.
<https://www.bls.gov/news.release/jolts.t16.htm>

⁹² The labor rate for inspectors is based on Occupational Employment Statistics group 45-2011, *Agricultural Inspectors*. Agricultural inspectors inspect agricultural commodities, processing equipment, facilities, and fish and logging operations to ensure compliance with regulations and laws governing health, quality, and safety.

34.63% benefits. The total annual cost for all inspectors working for USDA-accredited certifying agents is \$210,860, at their respective wage rates and benefits.^{93,94}

Producers and handlers.

Domestic and foreign producers and handlers seeking organic certification must submit an OSP that details the practices and activities specific to their operation. Once certified, operations are required to update any changes in their operation or practices to their certifying agent at least annually.

Uncertified Handlers. This rulemaking requires that operations that facilitate the sale or trade of organic products—including, but not limited to, certain brokers, importers, and traders—obtain organic certification and submit and maintain an OSP. AMS estimates that 1,985 domestic⁹⁵ and 1,379 foreign-based⁹⁶ operations will need to become certified as a result of the rule. Traders and brokers do not farm or manufacture organic products, so the OSPs for traders and brokers will address fewer sections of USDA organic regulations than OSPs for operations that produce or manufacture organic products. Certifying agents customize the format of the OSP to cover standards applicable to the operations seeking certification. Therefore, AMS estimates that preparation of an initial OSP will require 40 reporting hours, plus 10 hours of annual

⁹³ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020.

<https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents:

<https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>

⁹⁴ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

⁹⁵ Please refer to the “Applicability and Exemptions from Certification (§§ 205.100–101)” chapter in the Regulatory Impact Analysis (RIA) for an explanation of how previously excluded domestic handlers were estimated.

⁹⁶ AMS assumes the 1,985 domestic excluded operations represent 59% of the global total benchmarked 59%/41% ratio of domestic to foreign operations and certifying agents. Therefore, AMS estimate there are an additional 1,379 foreign formerly excluded operations, for a total of 3,364 new handlers that will need organic certification.

recordkeeping. The estimated annual reporting burden for each entity to update its OSP in future years is 20 hours (See Summary Table 3a: *Uncertified Handlers*).

All operations that export organic products to the United States must request an NOP Import Certificate from their certifying agent. Further, operations that import organic products must verify and reconcile each shipment with its associated NOP Import Certificate and verify that organic integrity was maintained throughout the import process. In addition, domestic and foreign handlers that must obtain organic certification as a result of this rulemaking will also need to comply with the labeling requirements for nonretail containers.

SUMMARY TABLE 3a: Uncertified Handlers						
Respondent Categories	Number of Respondents	Wages + Benefits	Total hours per	Total cost per respondent	Total All Hours	Total All Costs
Formerly Excluded Handlers - Domestic	1,985	\$48.64	50.97	\$2,478.80	101,166.47	\$4,920,414.48
Formerly Excluded Handlers - Foreign	1,379	\$34.95	53.42	\$1,867.02	73,660.94	\$2,574,623.40
All Uncertified Handlers	3,364				174,827.41	\$7,495,037.88

AMS estimates the annual paperwork impact for each domestic handler to prepare their initial organic system plan, verify and reconcile imported shipments with their respective NOP Import Certificates, and verify that the organic integrity of the product was maintained through shipping is \$2,478.80. This is based on an estimated 50.97 labor hours at \$48.64 per labor hour, including 31.7% benefits. The total cost to all previously

uncertified domestic handlers is \$4,920,415. This cost is based on 101,166.47 total labor hours at \$48.64 per labor hour, including 31.7% benefits.⁹⁷

AMS estimates the annual paperwork impact for each foreign-based handler to prepare their initial organic system plan and to work with their certifying agent to prepare NOP Import Certificates for the products they export is \$1,867.02. This is based on an estimated 53.42 labor hours per year at \$34.95 per labor hour, which includes 34.63% for benefits. The total cost to all previously uncertified foreign handlers is \$2,574,623.40. This cost is based on 73,660.94 total labor hours at \$34.95 per labor hour, which includes 34.63% for benefits. Total costs to the 3,364 previously uncertified handlers, domestic and foreign, is \$7,495,038, based on 174,827 total labor hours at their respective domestic and foreign wage rates and benefits. This cost is to prepare and keep initial OSPs and related records, and to prepare, verify, and reconcile NOP Import Certificates for compliance.^{98,99}

Certified Operations and New Applicants under Current Rules. There currently are 44,725 organic operations worldwide that are certified to the USDA organic standards. Over the next 12 months, AMS expects 2,639 operations will seek organic certification, based on the 5.9% rate of growth in number of operations observed in the last 12 months under current rules. Therefore, AMS estimates that 27,945 operations based in the United States, and 19,419 operations based in foreign countries, including the respective applicants for certification, will be impacted by this rulemaking.¹⁰⁰

⁹⁷ For uncertified handlers, AMS chose to use the same labor rate as certified producers and handlers: Occupational Employment Statistics group 11-9013, *Farmers, Ranchers, and Other Agricultural Managers*.

⁹⁸ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020.

[https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD.agents:](https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD.agents)
<https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>

⁹⁹ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

¹⁰⁰ Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>

All currently certified organic operations and projected new applicants must describe in their OSP their procedures for monitoring, verifying, and demonstrating the organic status of their suppliers and products received to prevent organic fraud. All certified organic operations must also comply with revised nonretail container labeling requirements and must maintain all records about their organic production and/or handling for five years (§ 205.103(b)(3)).

In addition, AMS estimates a one-time paperwork burden of 11,800 hours for 5,900 producer group operations to prepare a detailed Internal Control System (ICS) for their OSP, including procedures to address conflicts of interest and manage the unique challenges of producer group oversight. In addition, training requirements for ICS personnel and producer group members are expanded to 29,500 hours annually (§§ 205.201, 205.400(g) and 205.403).¹⁰¹

SUMMARY TABLE 3b: Certified Organic Operations and New Applicants						
Respondent Categories	Number of Respondents	Wages + Benefits	Total hours/ respondent	Total cost/ respondent type	Total All Hours	Total All Costs
Certified Producers & Handlers - New and Existing Domestic	27,945	\$48.64	1.67	\$81.07	46,579.60	\$2,265,483.08
Certified Producers & Handlers - New and Existing Foreign	19,419	\$34.95	3.44	\$120.39	66,888.32	\$2,337,904.67

¹⁰¹ Meinshausen F., Richter, T., Blockeel, J., and Huber, B., *Group Certification: Internal Control Systems in Organic Agriculture: Significance, Opportunities and Challenges*, Research Institute of Organic Agriculture FiBL, March 2019.

All New and Existing Producers & Handlers	47,364		113,467. 92	\$4,603,388. 08
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AMS estimates that the average annual paperwork impact for domestic USDA-certified organic producers and handlers to develop fraud prevention procedures and to comply with nonretail container labeling requirements is \$81.07. This is based on an estimated 1.67 labor hours at \$48.64 per labor hour, including 31.7% benefits. The total cost for all domestic certified organic producers and handlers to comply with these new requirements is \$2,265,483.08. This cost is based on 46,579.60 labor hours at \$48.64 per labor hour, including 31.7% benefits.¹⁰²

AMS estimates the average annual paperwork impact for foreign-based USDA-certified organic producers and handlers to create fraud prevention procedures and to comply with nonretail container labeling requirements is \$120.39. This is based on an estimated 3.44 labor hours per year at \$34.95 per labor hour, including 34.63% benefits. The total cost for all foreign producers and handlers certified to the USDA organic standards is \$2,337,904.67. This cost is based on 66,888.32 labor hours year at \$34.95 per labor hour, including 34.63% benefits. The total cost for the 47,364 current and projected certified organic producers and handlers, domestic and foreign, is \$4,603,388.

¹⁰² The labor rate for producers and handlers is based on Occupational Employment Statistics group 11-9013, *Farmers, Ranchers, and Other Agricultural Managers*, who plan, direct, or coordinate the management or operation of farms, ranches, or other agricultural establishments.

This cost is based on 113,4677.92 labor hours at their respective domestic and foreign wages and benefits.^{103,104}

Foreign Governments.

The U.S. government, including the USDA and the U.S. Trade Representative, work closely together to implement processes that determine the equivalence of foreign organic certification programs and then negotiate an arrangement or agreement as appropriate.¹⁰⁵ Formerly, the organic regulations only addressed this authority in general terms under § 205.500(c) but did not describe the criteria, scope, and other parameters to establish, oversee, or terminate such arrangements or agreements. The rulemaking describes equivalence determinations in more detail; this creates a new type of PRA respondent category. The rulemaking allows an equivalence determination if the U.S. government determines that the technical requirements and conformity assessment system under which foreign products labeled as organic are produced and handled are at least equivalent to the requirements of the OFPA and the USDA organic regulations. The rulemaking requires periodic assessment.

AMS expects these periodic peer review assessments will be similar in depth and frequency to the audits of USDA-accredited certifying agents and estimates a comparable level of reporting and recordkeeping burden by foreign governments with which USDA has negotiated trade arrangements or agreements. AMS estimates the collection cost for the periodic review of a single foreign government is \$602. This cost is based on 7.5 reporting labor hours averaged as needed and an estimated 10 hours of annual

¹⁰³ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020.

<https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents:

<https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>

¹⁰⁴ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

¹⁰⁵ The United States currently has organic trade arrangements with Canada, the European Union, the United Kingdom, Israel, Japan, New Zealand, South Korea, Taiwan, and Switzerland.

recordkeeping per foreign government per year at \$24.59 per labor hour, including 34.63% benefits, for a total salary component of \$602.06 per year reviewed. The total cost for foreign governments to be assessed for a trade arrangement or agreement is \$4,816. This cost is averaged as 140 total labor hours for all foreign governments at \$24.59 per labor hour, including 34.63% benefits.^{106,107}

Total (Domestic and Foreign) Information Collection Cost (Reporting and Recordkeeping) of Rulemaking: \$14,416,897 (Also, see Summary Table 4: *All Reporting and Recordkeeping Hours and Costs, and All Domestic Reporting and Recordkeeping Hours and Costs*)

Total All Reporting Burden Cost: \$12,454,097

Estimate of Burden: Public reporting burden for the collection of information is estimated to average 0.56 hours per year per response.

Respondents: Certifying agents, certified operations, inspectors, and foreign governments.

Estimated Number of Reporting Respondents: 51,091

Estimated Number of Reporting Responses: 566,387

Estimated Total Annual Burden on Reporting Respondents: 318,859 hours

Estimated Total Annual Reporting Responses per Reporting Respondents: 11.09

reporting responses per reporting respondents

Total All Recordkeeping Burden Cost: \$1,962,800

Estimate of Burden: Public recordkeeping burden is estimated to be an annual total of 0.90 hours per year per respondent.

¹⁰⁶ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020.

<https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents:
<https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>

¹⁰⁷ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

Respondents: Certifying agents, certified operations, and foreign governments.

Estimated Number of Recordkeeping Respondents: 50,811

Estimated Total Recordkeeping Burden on Respondents: 45,636 hours.

Estimated Total Recordkeeping Responses per Recordkeeping Respondents: 1

recordkeeping response per recordkeeping respondents

Total Domestic Only Information Collection Cost (Reporting and Recordkeeping) of Rulemaking: \$7,934,528

Total Domestic Only Reporting Burden Cost: \$6,627,301

Estimate of Burden: Public domestic only reporting burden is estimated to be an annual total 0.43 hours per year per domestic respondent

Respondents: Certifying agents, certified operations, and inspectors.

Estimated Number of Domestic Reporting Respondents: 30,123

Estimated Number of Domestic Reporting Responses: 334,168

Estimated Total Annual Reporting Burden on Domestic Respondents: 145,315

hours

Estimated Total Domestic Reporting Responses per Reporting Respondents: 11.09

reporting response per reporting respondents

Total Domestic Only Recordkeeping Burden Cost: \$1,307,227

Estimate of Burden: Public domestic only recordkeeping burden is estimated to be an annual total of 1 hours per year per respondent.

Respondents: Certifying agents and certified operations.

Estimated Number of Domestic Recordkeeping Respondents: 29,975

Estimated Total Annual Recordkeeping Burden on Domestic Respondents:

26,878 hours.

Estimated Number of Domestic Recordkeeping Responses: 29,929

Estimated Total Domestic Recordkeeping Responses per Recordkeeping

Respondents: 1 recordkeeping response per recordkeeping respondents

Summary Table 4: All Hours and Costs, All Domestic Hours and Costs, and All Foreign Hours and Costs				
	Hours	Costs	# of Respondents	Respondent Types
Total for All (Reporting & Recordkeeping)	364,495	\$14,416,897	51,091	Certifying agents, certified operations, inspectors, and foreign governments
All Reporting	318,859	\$12,454,097	51,091	Certifying agents, certified operations, inspectors, and foreign governments
All Recordkeeping	45,636	\$1,962,800	50,811	Certifying agents, certified operations, and foreign governments.
Just Domestic-All (Reporting & Recordkeeping)	172,193	\$7,934,528	30,123	Certifying agents, certified operations, and inspectors
Just Domestic Reporting	145,315	\$6,627,301	30,123	Certifying agents, certified operations, and inspectors
Just Domestic Recordkeeping	26,878	\$1,307,227	29,975	Certifying agents and certified operations
Just Foreign-All (Reporting & Recordkeeping)	192,301	\$6,482,369	20,968	Certifying agents, certified operations, inspectors, and foreign governments
Just Foreign Reporting	173,543	\$5,826,795	20,968	Certifying agents, certified operations, inspectors, and foreign governments
Just Foreign Recordkeeping	18,758	\$655,573	20,836	Certifying agents, certified operations, and foreign governments

E. Executive Order 13175

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments, or proposed legislation. Additionally, other policy statements or actions that have substantial direct effects on one or more Indian Tribes, the relationship between the Federal Government and Indian Tribes, or on the

distribution of power and responsibilities between the Federal Government and Indian Tribes also require consultation.

AMS hosted a virtual tribal listening session on April 9, 2020, to discuss the Strengthening Organic Enforcement proposed rule and upcoming public comment opportunity. AMS has not received comments from Tribes during the rulemaking process. AMS conducted an analysis of possible Tribal impacts and determined that any impact is most likely to be positive. AMS finds oversight protections and fraud deterrence actions that will have positive benefits for organic producers extend to any Tribal organic producers. Further, the specific provisions related to grower groups may benefit small producers in a Tribe who wish to join together under a shared certification for market development purposes.

If a tribe requests consultation in the future, AMS will work with the Office of Tribal Relations to ensure meaningful consultation is provided. AMS also stands ready to provide technical assistance to Tribes and operators wishing to participate in the organic certification process.

F. Executive Order 13132

Executive Order 13132 mandates that federal agencies consider how their policymaking and regulatory activities impact the policymaking discretion of States and local officials and how well such efforts conform to the principles of federalism defined in said order. This executive order only pertains to regulations with clear federalism implications.

AMS has determined that this rulemaking conforms with the principles of federalism described in E.O. 13132. The rule does not impose substantial direct costs or effects on States, does not alter the relationship between States and the federal government, and does not alter the distribution of powers and responsibilities among the various levels of government. States had the opportunity to comment on the proposed rule. No States

provided public comment on the federalism implications of this rule. Therefore, AMS has concluded that this rulemaking does not have federalism implications.

G. Civil Rights Impact Analysis

AMS has reviewed this rulemaking in accordance with the Department Regulation 4300-4, Civil Rights Impact Analysis, to address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, AMS determined that this rule will affect certifying agents and organic inspectors, handlers of organic products, and organic producers. AMS also determined that this rule has no potential for affecting producers, handlers, certifying agents, or inspectors in protected groups differently than the general population of producers, handlers, certifying agents, or inspectors.

Protected individuals have the same opportunity to participate in NOP as non-protected individuals. The USDA organic regulations prohibit discrimination by certifying agents. Specifically, § 205.501(d) of the current regulations for accreditation of certifying agents provides that "No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status." Section 205.501(a)(2) requires "certifying agents to demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart" including the prohibition on discrimination. The granting of accreditation to certifying agents under § 205.506 requires the review of information submitted by the certifying agent and an on-site review of the certifying agent's client operation. Further, if certification is denied, § 205.405(d) requires that the certifying agent notify the applicant of their right to file an appeal to the AMS Administrator in accordance with § 205.681.

These regulations provide protections against discrimination, thereby permitting all producers, regardless of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status, who voluntarily choose to adhere to the rule and qualify, to be certified as meeting NOP requirements by an accredited certifying agent. This action in no way changes any of these protections against discrimination.

H. Related Documents

Documents related to this rule include the Organic Foods Production Act of 1990, as amended, (7 U.S.C. 6501–6524) and its implementing regulations (7 CFR part 205). On August 5, 2020, AMS published the proposed rule (85 FR 47536) to notify the public of and request comments on the potential changes to the organic regulations discussed in this rulemaking.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agricultural Commodities, Agriculture, Animals, Archives and records, Fees, Imports, Labeling, Livestock, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 205 as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6524.

2. Section 205.2 is amended by:

- a. Adding in alphabetical order the terms “Adverse action”, “Certification activity”, “Certification office”, “Certification review”, and “Conformity assessment system”;

- b. Revising the terms “Handle”, “Handler”, and “Handling operation”;
- c. Adding in alphabetical order the terms “Internal control system”, “Organic exporter”, “Organic fraud”, “Organic importer”, “Organic Integrity Database”, “Producer group member”, “Producer group operation”, “Producer group production unit”, and “Retail establishment”;
- d. Removing the terms “Retail food establishment”; and
- e. Adding in alphabetical order the terms “Supply chain traceability audit”, “Technical requirements”, and “Unannounced inspection”.

The revisions and additions read as follows:

§ 205.2 Terms defined.

* * * * *

Adverse action. A noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease and desist notice; or a civil penalty.

* * * * *

Certification activity. Any business conducted by a certifying agent, or by a person acting on behalf of a certifying agent, including but not limited to: certification management; administration; application review; inspection planning; inspections; sampling; inspection report review; material review; label review; records retention; compliance review; investigating complaints and taking adverse actions; certification decisions; and issuing transaction certificates.

Certification office. Any site or facility where certification activities are conducted, except for certification activities that occur at certified operations or applicants for certification, such as inspections and sampling.

* * * * *

Certification review. The act of reviewing and evaluating a certified operation or applicant for certification and determining compliance or ability to comply with the USDA organic regulations. This does not include performing an inspection.

* * * * *

Conformity assessment system. All activities, including oversight, accreditation, compliance review, and enforcement, undertaken by a government to ensure that the applicable technical requirements for the production and handling of organic agricultural products are fully and consistently applied.

* * * * *

Handle. To sell, process, or package agricultural products, including but not limited to trading, facilitating sale or trade on behalf of a seller or oneself, importing to the United States, exporting for sale in the United States, combining, aggregating, culling, conditioning, treating, packing, containerizing, repackaging, labeling, storing, receiving, or loading.

Handler. Any person that handles agricultural products, except final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation that handles agricultural products, except final retailers of agricultural products that do not process agricultural products.

* * * * *

Internal control system. An internal quality management system that establishes and governs the review, monitoring, training, and inspection of the producer group operation, and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations.

* * * * *

Organic exporter. The final certified exporter of the organic agricultural product, who facilitates the trade of, consigns, or arranges for the transport/shipping of the organic agricultural product from a foreign country to the United States.

Organic fraud. Deceptive representation, sale, or labeling of nonorganic agricultural products or ingredients as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

Organic importer. The operation responsible for accepting imported organic agricultural products within the United States and ensuring NOP Import Certificate data are entered into the U.S. Customs and Border Protection import system of record.

Organic Integrity Database. The National Organic Program's electronic, web-based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or the tool's successors.

* * * * *

Producer group member. An individual engaged in the activity of producing or harvesting agricultural products as a member of a producer group operation.

Producer group operation. A producer, organized as a person, consisting of producer group members and production units in geographic proximity governed by an internal control system under one organic system plan and certification.

Producer group production unit. A defined subgroup of producer group members in geographic proximity within a single producer group operation that use shared practices and resources to produce similar agricultural products.

* * * * *

Retail establishment. Restaurants, delicatessens, bakeries, grocery stores, or any retail business with a restaurant, delicatessen, bakery, salad bar, bulk food self-service station, or other eat-in, carry-out, mail-order, or delivery service of raw or processed agricultural products.

* * * * *

Supply chain traceability audit. The process of identifying and tracking the movement, sale, custody, handling, and organic status of an agricultural product along a supply chain to verify the agricultural product's compliance with this part.

* * * * *

Technical requirements. A system of relevant laws, regulations, regulatory practices, standards, policies, and procedures that address the certification, production, and handling of organic agricultural products.

* * * * *

Unannounced inspection. The act of examining and evaluating all or a portion of the production or handling activities of a certified operation without advance notice to determine compliance with the Act and the regulations in this part.

* * * * *

3. Section 205.100 is amended by revising paragraph (a) and paragraph (c) introductory text to read as follows:

§ 205.100 What has to be certified.

(a) Except for the exempt operations described in § 205.101, each operation or portion of an operation that produces or handles agricultural products intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

* * * * *

(c) Any person or responsibly connected person that:

* * * * *

4. Revise § 205.101 to read as follows:

§ 205.101 Exemptions from certification.

The following operations in paragraphs (a) through (h) of this section are exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part, the applicable labeling requirements of subpart D of this part, and any requirements described in paragraphs (a) through (i) of this section.

(a) A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually.

(b) A retail establishment that does not process organically produced agricultural products.

(c) A retail establishment that processes, at the point of final sale, agricultural products certified under this part as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

(d) A handling operation that only handles agricultural products that contain less than 70 percent organic ingredients (as described in § 205.301(d)) or that only identifies organic ingredients on the information panel.

(e) An operation that only receives, stores, and/or prepares for shipment, but does not otherwise handle, organic agricultural products that:

(1) Are enclosed in sealed, tamper-evident packages or containers prior to being received or acquired by the operation; and

(2) Remain in the same sealed, tamper-evident packages or containers and are not otherwise handled while in the control of the operation.

(f) An operation that only buys, sells, receives, stores, and/or prepares for shipment, but does not otherwise handle, organic agricultural products already labeled for retail sale that:

(1) Are enclosed in sealed, tamper-evident packages or containers that are labeled for retail sale prior to being received or acquired by the operation; and

(2) Remain in the same sealed, tamper-evident packages or containers that are labeled for retail sale and are not otherwise handled while in the control of the operation.

(g) A Customs broker (per 19 CFR 111.1) that only conducts customs business but does not otherwise handle organic agricultural products.

(h) An operation that only arranges for the shipping, storing, transport, or movement of organic agricultural products but does not otherwise handle organic products.

(i) Recordkeeping by exempt operations.

(1) Exempt operations described in paragraphs (a) and (c) through (f) of this section must make available to representatives of the Secretary, upon request, records that:

(i) Demonstrate that agricultural products identified as organic were organically produced and handled; and

(ii) Verify quantities of organic agricultural products received and shipped or sold

(2) All records described in this section must be maintained for no less than 3 years beyond their creation, and the operations must allow representatives of the Secretary and the applicable State organic programs' governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

5. Section 205.103 is amended by:

a. Revising paragraph (b)(2);

b. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5); and

c. Adding new paragraph (b)(3).

The revision and addition read as follows:

§ 205.103 Recordkeeping by certified operations.

* * * * *

(b) * * *

(2) Fully disclose all activities and transactions of the certified operation, in sufficient detail as to be readily understood and audited; records must span the time of purchase or acquisition, through production, to sale or transport and be traceable back to the last certified operation;

(3) Include audit trail documentation for agricultural products handled or produced by the certified operation and identify agricultural products on these records as “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or similar terms, as applicable;

* * * * *

6. Section 205.201 is amended by:

- a. Removing the words “or excluded” in paragraph (a) introductory text;
- b. Revising paragraph (a)(3); and
- c. Adding paragraph (c).

The revision and addition to read as follows:

§ 205.201 Organic production and handling system plan.

(a) * * *

(3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented. This must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of agricultural products received, and to prevent organic fraud, as appropriate to the certified operation’s activities, scope, and complexity;

* * * * *

(c) In addition to paragraph (a) of this section, a producer group operation's organic system plan must describe its internal control system. The description of the internal control system must:

- (1) Define the organizational structure, roles, and responsibilities of all personnel;
- (2) Identify producer group production units and locations;
- (3) Describe measures to protect against potential conflicts of interest and protect internal control system personnel from retribution;
- (4) Define geographic proximity criteria for producer group members and producer group production units;
- (5) Describe procedures for accepting new members into the producer group operation, including initial inspection and compliance determination;
- (6) Describe characteristics of high-risk producer group members and producer group production units;
- (7) Describe how shared resources, including production practices and inputs, are procured and provided to all producer group members and personnel;
- (8) Describe how training, education, and technical assistance is provided to producer group members and internal control system personnel;
- (9) Describe the system of records used to demonstrate compliance with this part, including traceability and mass-balance audits; and
- (10) Describe how internal monitoring, surveillance, inspection, sanctions, and auditing are used to assess the compliance of all producer group members.

7. Add § 205.273 to subpart C to read as follows:

§ 205.273 Imports to the United States.

Each shipment of organic agricultural products imported into the United States must be certified pursuant to subpart E of this part, labeled pursuant to subpart D of this part, be declared as organic to U.S. Customs and Border Protection, and be associated with valid NOP Import Certificate data.

(a) Persons exporting organic agricultural products to the United States must request an NOP Import Certificate from a certifying agent prior to their export. Only certifying agents accredited by the USDA or foreign certifying agents authorized under an organic trade arrangement or agreement may issue an NOP Import Certificate.

(b) The certifying agent must review an NOP Import Certificate request and determine whether the export complies with the USDA organic regulations. The certifying agent must have and implement a documented organic control system for intaking and approving or rejecting the validity of an NOP Import Certificate request. The certifying agent shall issue the NOP Import Certificate through the Organic Integrity Database only if the export complies with the USDA organic regulations.

(c) Each compliant organic import must be declared as organic to U.S. Customs and Border Protection by entering NOP Import Certificate data into the U.S. Customs and Border Protection's Automated Commercial Environment system. Organic imports must be clearly identified and marked as organic on all import documents including but not limited to invoices, packing lists, bills of lading, and U.S. Customs and Border Protection entry data. Only NOP Import Certificate data generated by the Organic Integrity Database are valid.

(d) Upon receiving a shipment with organic agricultural products, the organic importer must ensure the import is accompanied by accurate NOP Import Certificate data and must verify that the shipment has had no contact with prohibited substances pursuant to § 205.272 or exposure to ionizing radiation pursuant to § 205.105, since export. The

organic importer must have a documented organic control system to conduct this verification.

8. Amend § 205.300 by revising paragraph (c) to read as follows:

§ 205.300 Use of the term, “organic.”

* * * * *

(c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part, labeled pursuant to this subpart D, and must comply with the requirements in § 205.273.

* * * * *

9. Amend § 205.301 by revising paragraphs (f)(2) and (3) to read as follows:

§ 205.301 Product composition.

* * * * *

(f) * * *

(2) Be processed using ionizing radiation, pursuant to § 205.105(f);

(3) Be produced using sewage sludge, pursuant to § 205.105(g);

* * * * *

10. Amend § 205.302 by revising paragraphs (a)(1) through (3) to read as follows:

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) * * *

(1) Dividing the total net weight of the combined organic ingredients at formulation by the total weight of all ingredients of the product at formulation. Water and salt added as ingredients at formulation are excluded from the calculation.

(2) Dividing the total fluid volume of the combined organic ingredients at formulation by the total fluid volume of all ingredients of the product at formulation if the product and ingredients are liquid. Water and salt added as ingredients at formulation are excluded from the calculation. If the liquid product is identified on the principal

display panel or information panel as being reconstituted from concentrates, the calculation should be made based on single-strength concentrations of all ingredients.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined net weight of the solid organic ingredients and the net weight of the liquid organic ingredients at formulation by the total weight of all ingredients of the product at formulation. Water and salt added as ingredients at formulation are excluded from the calculation.

* * * * *

11. Revise § 205.307 to read as follows:

§ 205.307 Labeling of nonretail containers.

(a) Nonretail containers used to ship or store certified organic agricultural products must display:

(1) Identification of the product as organic; and

(2) The production lot number, shipping identification, or other unique information that links the container to audit trail documentation.

(b) Audit trail documentation for nonretail containers must identify the last certified operation that handled the agricultural product.

(c) Paragraph (a)(1) of this section does not apply to nonretail containers used to ship or store agricultural products packaged for retail sale with organic identification visible on the retail label.

(d) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: Provided, that, the shipping containers and shipping documents accompanying such organic products are clearly marked “For Export Only” and: Provided further, that proof of such container marking

and export must be maintained by the handler in accordance with recordkeeping requirements for exempt operations under § 205.101.

12. Section 205.310 is amended by revising the section heading and paragraphs (a) and (b) to read as follows:

§ 205.310 Agricultural products produced or processed by an exempt operation.

(a) An agricultural product organically produced or processed by an exempt operation must not:

(1) Display the USDA seal or any certifying agent's seal or other identifying mark which represents the exempt operation as a certified organic operation; or

(2) Be represented as a certified organic product or certified organic ingredient to any buyer.

(b) An agricultural product organically produced or processed by an exempt operation may be identified as an organic product or organic ingredient in a multi-ingredient product produced by the exempt operation. Such product or ingredient must not be identified or represented as “organic” in a product processed by others.

* * * * *

13. Section 205.400 is amended by:

a. Removing “§ 205.200” and adding in its place “§ 205.201” in paragraph (b);
and

b. Adding paragraph (g).

The addition reads as follows:

§ 205.400 General requirements for certification.

* * * * *

(g) In addition to paragraphs (a) through (f) of this section, a producer group operation must:

(1) Be organized as a person;

- (2) Use centralized processing, distribution, and marketing facilities and systems;
- (3) Be organized into producer group production units;
- (4) Maintain an internal control system to implement the practices described in § 205.201(c) and ensure compliance with this part;
- (5) Ensure that all agricultural products sold, labeled, or represented as organic are produced only by producer group members using land and facilities within the certified operation;
- (6) Ensure that producer group members do not sell, label, or represent their agricultural products as organic outside of the producer group operation unless they are individually certified;
- (7) Report to the certifying agent, at least annually, the name and location of all producer group members and producer group production units, the agricultural products produced, estimated yields, and size of production areas;
- (8) Conduct internal inspections of each producer group member, at least annually, by internal inspectors with the member present, which must include mass-balance audits and reconciliation of each producer group member's and each producer group production unit's yield and group sales;
- (9) Implement recordkeeping requirements to ensure traceability from production at each producer group member and production unit through handling to sale and transport;
- (10) Implement procedures to ensure all production and handling by the producer group operation is compliant with the USDA organic regulations and the Act; and
- (11) Address any other terms or conditions determined by the Administrator to be necessary to enforce compliance with the USDA organic regulations and the Act.

§ 205.401 [Amended]

14. Amend § 205.401 in paragraph (a) by removing “§ 205.200” and adding in its place “§ 205.201”.

15. Section 205.403 is amended by:

- a. Redesignating paragraph (a)(2) as paragraph (a)(3);
- b. Adding new paragraph (a)(2);
- c. Redesignating paragraphs (b) through (e) as paragraphs (c) through (f);
- d. Adding new paragraph (b);
- e. In newly redesignated paragraph (d)(2), removing “§ 205.200” and adding in its place “§ 205.201”; and
- f. Adding paragraphs (d)(4) and (5).

The additions read as follows:

§ 205.403 On-site inspections.

(a) * * *

(2) Inspections of a producer group operation must:

(i) Assess the internal control system’s compliance, or ability to comply, with the requirements of § 205.400(g)(8). This must include review of the internal inspections conducted by the internal control system.

(ii) Conduct witness audits of internal control system inspectors performing inspections of the producer group operation.

(iii) Individually inspect at least 1.4 times the square root or 2% of the total number of producer group members, whichever is higher. All producer group members determined to be high risk by the certifying agent must be inspected. At least one producer group member in each producer group production unit must be inspected.

(iv) Inspect each handling facility.

* * * * *

(b) *Unannounced inspections.* (1) A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number.

(2) Certifying agents must be able to conduct unannounced inspections of any operation they certify and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections.

* * * * *

(d) * * *

(4) Mass-balances, in that quantities of organic product and ingredients produced or purchased account for organic product and ingredients used, stored, sold, or transported (that is, inputs account for outputs); and

(5) That organic products and ingredients are traceable by the operation from the time of purchase or acquisition through production to sale or transport; and that the certifying agent can verify compliance back to the last certified operation.

* * * * *

16. Section § 205.404 is amended by revising paragraph (b), redesignating paragraph (c) as paragraph (d), and adding a new paragraph (c).

The revision and addition read as follows:

§ 205.404 Certificates of organic operation.

* * * * *

(b) The certifying agent must issue a certificate of organic operation. The certificate of organic operation must be generated from the Organic Integrity Database and may be provided to certified operations electronically.

(c) In addition to the certificate of organic operation provided for in paragraph (b) of this section, a certifying agent may issue its own addenda to the certificate of organic operation. If issued, any addenda must include:

- (1) Name, address, and contact information for the certified operation;
- (2) The certified operation's unique ID number/code that corresponds to the certified operation's ID number/code in the Organic Integrity Database;
- (3) A link to the Organic Integrity Database or a link to the certified operation's profile in the Organic Integrity Database, along with a statement, "You may verify the certification of this operation at the Organic Integrity Database," or a similar statement;
- (4) Name, address, and contact information of the certifying agent; and
- (5) "Addendum issue date."

* * * * *

§ 205.405 [Amended]

17. Amend § 205.405 by removing paragraph (c)(3).

18. Amend 205.406 by revising paragraphs (a) and (b) to read as follows:

§ 205.406 Continuation of certification.

(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information to the certifying agent:

(1) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the organic system plan submitted during the previous year;

(2) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to § 205.201;

(3) Any additions to or deletions from the information required pursuant to § 205.401(b); and

(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

(b) The certifying agent must arrange and conduct an on-site inspection, pursuant to § 205.403, of the certified operation at least once per calendar year.

* * * * *

§ 205.500 [Amended]

19. Amend § 205.500 by removing paragraph (c).

20. Section 205.501 is amended by:

- a. Revising paragraphs (a)(4), (5), (6), (10), (13), and (15);
- b. Redesignating paragraph (a)(21) as paragraph (a)(23); and
- c. Adding new paragraph (a)(21) and paragraph (a)(22).

The revisions and additions read as follows:

§ 205.501 General requirements for accreditation.

(a) * * *

(4) Continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the USDA organic standards.

(i) Certifying agents must demonstrate that all inspectors, including staff, volunteers, and contractors, have the relevant knowledge, skills, and experience required to inspect operations of the scope and complexity assigned and to evaluate compliance with the applicable regulations of this part.

(A) Certifying agents must demonstrate that inspectors continuously maintain adequate knowledge and skills about the current USDA organic standards, production and handling practices, certification and inspection, import and/or export requirements, traceability audits, mass-balance audits, written and oral communication skills, sample collection, investigation techniques, and preparation of technically accurate inspection documents.

(B) All inspectors must demonstrate successful completion of training that is relevant to inspection. Inspectors with less than one year of inspection experience must complete at least 50 hours of training within their first year and prior to performing

inspections independently. Inspectors with one or more years of inspection experience must annually complete at least 10 hours of training if inspecting one area of operation (as defined at § 205.2) and an additional 5 hours of training for each additional area of operation inspected.

(C) Certifying agents must demonstrate that inspectors have a minimum of 2,000 hours of experience relevant to the scope and complexity of operations they will inspect before assigning initial inspection responsibilities.

(ii) Certifying agents must demonstrate that all certification review personnel, including staff, volunteers, or contractors, have the knowledge, skills, and experience required to perform certification review of operations of the scope and complexity assigned and to evaluate compliance with the applicable regulations of this part.

(A) Certifying agents must demonstrate that all certification review personnel continuously maintain adequate knowledge and skills in the current USDA organic standards, certification and compliance processes, traceability audits, mass-balance audits, and practices applicable to the type, volume, and range of review activities assigned.

(B) All certification review personnel must demonstrate successful completion of training that is relevant to certification review. Certification review personnel with less than one year of certification review experience must complete at least 50 hours of training within their first year performing certification review. Certification review personnel with one or more years of certification review experience must annually complete at least 10 hours of training if conducting certification review related to one area of operation and an additional 5 hours of training for each additional area of operation.

(iii) Certifying agents must maintain current training requirements, training procedures, and training records for all inspectors and certification review personnel.

(5) Demonstrate that all persons with inspection or certification review responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. Sufficient expertise must include knowledge of certification to USDA organic standards and evidence of education, training, or professional experience in the fields of agriculture, science, or organic production and handling that relates to assigned duties.

(6) Conduct an annual performance evaluation of all persons who conduct inspections, certification review, or implement measures to correct any deficiencies in certification services.

(i) Witness inspections—certifying agents must ensure that each inspector is evaluated while performing an inspection at least once every three years, or more frequently if warranted. Inspectors with less than three years of inspection experience must undergo a witness inspection annually. Witness inspections must be performed by certifying agent personnel who are qualified to evaluate inspectors.

(ii) Certifying agents must maintain documented policies, procedures, and records for annual performance evaluations and witness inspections.

* * * * *

(10) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (except for the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except:

(i) For information that must be made available to any member of the public, as provided for in § 205.504(b)(5);

(ii) For enforcement purposes, certifying agents must exchange any compliance-related information that is credibly needed to certify, decertify, or investigate an

operation, including for the purpose of verifying supply chain traceability and audit trail documentation; and

(iii) If a certified operation's proprietary business information is compliance-related and thus credibly needed to certify, decertify, or investigate that operation, certifying agents may exchange that information for the purposes of enforcing the Act, but the information in question still retains its proprietary character even after it is exchanged and all of the certifying agents that are involved in the exchange still have a duty to preserve the confidentiality of that information after the exchange.

* * * * *

(13) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to § 205.500. Certifying agents must provide information to other certifying agents to ensure organic integrity or to enforce organic regulations, including to verify supply chain integrity, authenticate the organic status of certified products, and conduct investigations;

* * * * *

(15) Maintain current and accurate data in the Organic Integrity Database for each operation which it certifies;

* * * * *

(21) Conduct risk-based supply chain traceability audits as described in the criteria and procedures for supply chain audits, per § 205.504(b)(7), and share audit findings with other certifying agents as needed to determine compliance, per paragraph (a)(13) of this section.

(22) Notify AMS not later than 90 calendar days after certification activities begin in a new certification office. The notification must include the countries where the certification activities are being provided, the nature of the certification activities, and the qualifications of the personnel providing the certification activities.

* * * * *

21. Section 205.504 is amended by revising the introductory text and paragraph (b)(4) and adding paragraphs (b)(7) and (8) to read as follows:

§ 205.504 Evidence of expertise and ability.

A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§ 205.100 and 205.101, 205.201 through 205.203, 205.300 through 205.303, 205.400 through 205.406, and 205.661 through 205.663; and its ability to comply with the requirements for accreditation set forth in § 205.501:

* * * * *

(b) * * *

(4) A copy of the procedures to be used for sharing information with other certifying agents and for maintaining the confidentiality of any business-related information as set forth in § 205.501(a)(10);

* * * * *

(7) A copy of the criteria to identify high-risk operations and agricultural products for supply chain traceability audits; and procedures to conduct risk-based supply chain traceability audits, as required in § 205.501(a)(21); and procedures to report credible evidence of organic fraud to the Administrator.

(8) A copy of reasonable decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation.

* * * * *

22. Add § 205.511 to subpart F to read as follows:

§ 205.511 Accepting foreign conformity assessment systems.

(a) Foreign product may be certified under the USDA organic regulations by a USDA-accredited certifying agent and imported for sale in the United States. Foreign product that is produced and handled under another country's organic certification program may be sold, labeled, or represented in the United States as organically produced if the U.S. Government determines that such country's organic certification program provides technical requirements and a conformity assessment system governing the production and handling of such products that are at least equivalent to the requirements of the Act and the regulations in this part.

(b) Countries desiring to establish eligibility of product certified under that country's organic certification program to be sold, labeled, or represented in the United States as organically produced may request equivalence determinations from AMS. A foreign government must maintain compliance and enforcement mechanisms to ensure that its organic certification program is fully meeting the terms and conditions of any equivalence determination provided by the U.S. Government pursuant to this section. To request an equivalence determination, the requesting country must submit documentation that fully describes its technical requirements and conformity assessment system. If the U.S. Government determines it can proceed, AMS will assess the country's organic certification program to evaluate if it is equivalent.

(c) USDA, working with other Federal agencies, will describe the scope of an equivalence determination.

(d) AMS will conduct regular reviews and reassessments of countries deemed equivalent to verify that the foreign government's technical requirements and conformity assessment system continue to be at least equivalent to the requirements of the Act and the regulations of this part, and will determine if the equivalence determination should be continued, amended, or terminated. AMS will determine the timing and scope of reviews and re-assessments based on, but not limited to, factors such as: the terms of the

equivalence determination, changes to the foreign country's technical requirements or conformity assessment system, the results of previous reviews and re-assessments, instances of suspected or verified noncompliance issues, the volume of trade, and other factors contributing to the risk level of the equivalence determination.

(e) The U.S. Government may terminate an equivalence determination if the terms or conditions established under the equivalence determination are not met; if AMS determines that the country's technical requirements and/or conformity assessment program are no longer equivalent; if AMS determines that the foreign government's organic control system is inadequate to ensure that the country's organic certification program is fully meeting the terms and conditions under the equivalence determination; or for other good cause.

23. Amend § 205.660 by redesignating paragraphs (c) and (d) as paragraphs (d) and (e) and adding new paragraph (c).

The addition reads as follows:

§ 205.660 General.

* * * * *

(c) The Program Manager may initiate enforcement action against any person who sells, labels, or provides other market information concerning an agricultural product if such label or information implies that such product is produced or handled using organic methods, if the product was produced or handled in violation of the Organic Foods Production Act or the regulations in this part.

* * * * *

24. Amend § 205.661 by revising the section heading to read as follows:

§ 205.661 Investigation.

* * * * *

25. Section 205.662 is amended by:

- a. Adding paragraph (e)(3);
- b. Revising the first sentence of paragraph (f)(1); and
- c. Revising paragraph (g)(1).

The addition and revisions read as follows:

§ 205.662 Noncompliance procedure for certified operations.

* * * * *

(e) * * *

(3) Within 3 business days of issuing a notification of suspension or revocation, or the effective date of an operation's surrender, the certifying agent must update the operation's status in the Organic Integrity Database.

(f) * * *

(1) A certified operation or a person responsibly connected with an operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification, or submit a request for eligibility to be certified. * * *

* * * * *

(g) * * *

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than the amount specified in 7 CFR 3.91(b)(1)(xxxvi) per violation.

* * * * *

26. Revise § 205.663 to read as follows:

§ 205.663 Mediation.

(a) A certifying agent must submit with its administrative policies and procedures: decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions per § 205.504(b)(8).

(b) A certified operation or applicant for certification may request mediation to resolve a denial of certification or proposed suspension or proposed revocation of certification issued by a certifying agent or State organic program.

(1) A certified operation or applicant for certification must submit any request for mediation in writing to the applicable certifying agent or State organic program within 30 calendar days of receipt of the notice of proposed suspension or proposed revocation of certification or denial of certification.

(2) A certifying agent or State organic program may accept or reject a request for mediation based on the decision criteria required in paragraph (a) of this section.

Certifying agents must document these criteria and how the certifying agent applied the criteria to the request.

(3) If a certifying agent rejects a mediation request, it must provide this rejection, and the justification for the rejection, in writing to the applicant for certification or certified operation. The rejection must include the right to request an appeal, pursuant to § 205.681, within 30 calendar days of the date of receipt of the written notification of rejection of the request for mediation.

(4) When an operation appeals a rejection of mediation, the adverse action which is contested must not be finalized during the appeal proceeding.

(c) Both parties must agree on the person conducting the mediation.

(d) If a State organic program is in effect, the parties must follow the mediation procedures established in the State organic program and approved by the Secretary.

(e) The parties to the mediation have a maximum of 30 calendar days from the start of mediation to reach an agreement. Successful mediation results in a settlement agreement agreed to in writing by both the certifying agent and the certified operation. If mediation is unsuccessful, the applicant for certification or certified operation has 30

calendar days from receipt of a written notice of termination of mediation to appeal the denial of certification or proposed suspension or revocation pursuant to § 205.681.

(f) Any settlement agreement reached through mediation must comply with the Act and the regulations in this part. The Program Manager may review any mediated settlement agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.

(g) The Program Manager may propose mediation and enter into a settlement agreement at any time to resolve any adverse action notice.

27. Amend § 205.665 by revising paragraph (a) to read as follows:

§ 205.665 Noncompliance procedure for certifying agents.

(a) *Notification.* (1) A written notification of noncompliance will be sent to the certifying agent when:

(i) An inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part; or

(ii) The Program Manager determines that the certification activities of the certifying agent, or any person performing certification activities on behalf of the certifying agent, are not compliant with the Act or the regulations in this part; or

(iii) The Program Manager determines that the certification activities at a certification office, and/in specific countries, are not compliant with the Act or the regulations in this part.

(2) Such notification must provide:

(i) A description of each noncompliance;

(ii) The facts upon which the notification of noncompliance is based; and

(iii) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.

* * * * *

28. Revise § 205.680 to read as follows:

§ 205.680 General.

(a) Persons subject to the Act who believe they are adversely affected by an adverse action of the National Organic Program's Program Manager may appeal such decision to the Administrator.

(b) Persons subject to the Act who believe they are adversely affected by an adverse action of a State organic program may appeal such decision to the State organic program's governing State official, who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.

(c) Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent may appeal such decision to the Administrator, *Except*, that, when the person is subject to an approved State organic program, the appeal must be made to the State organic program.

(d) Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent or a State organic program may request mediation as provided in § 205.663.

(e) All appeals must comply with the procedural requirements in § 205.681(c) and (d).

(f) All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts.

(g) All appeals must be reviewed, heard, and decided by persons not involved with the adverse action being appealed.

29. Amend § 205.681 by revising paragraph (a) introductory text and paragraphs (a)(2), (b), (c), and (d)(1) and (3) to read as follows:

§ 205.681 Appeals.

(a) *Adverse actions by certifying agents.* An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or proposed revocation of certification to the Administrator, *Except*, that, when the applicant or certified operation is subject to an approved State organic program, the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary.

* * * * *

(2) If the Administrator or State organic program denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification unless the parties resolve the issues through settlement, or the appellant waives or does not timely request a hearing. Such proceeding must be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, subpart H, or the State organic program's rules of procedure.

(b) *Adverse actions by the NOP Program Manager.* A person affected by an adverse action, as defined by § 205.2, issued by the NOP Program Manager, may appeal to the Administrator.

(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, a certifying agent will continue its accreditation, or an operation will continue its certification, a civil penalty will be withdrawn, and a cease and desist notice will be withdrawn, as applicable to the operation.

(2) If the Administrator denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the accreditation or certification and/or levy civil penalties unless the parties resolve the issues through settlement, the appellant waives a hearing, or the appellant does not timely request a hearing. Such proceeding must be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, subpart H.

(c) *Filing period.* An appeal must be filed in writing within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or by the State organic program. An adverse action will become final and nonappealable unless an appeal is timely filed.

(d) * * *

(1) Appeals to the Administrator and Requests for Hearing must be filed in writing and addressed to: 1400 Independence Ave., S.W., Room 2642, Stop 0268, Washington, D.C. 20250, or electronic transmission, NOPAppeals@usda.gov.

* * * * *

(3) All appeals must include a copy of the adverse action and a statement of the appellant's reasons for believing that the action was not proper or made in accordance with applicable program regulations.

Erin Morris,

*Associate Administrator,
Agricultural Marketing Service.*

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